IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	:	**Master Docket: Misc. No. 21-mc-1230-JFC**
	:	**MDL No. 3014**
	:	**CONSOLIDATED SECOND AMENDED CLASS ACTION COMPLAINT FOR MEDICAL MONITORING AND DEMAND FOR JURY TRIAL**
This Document Relates to: All Actions	:	

TABLE OF CONTENTS

TABLE OF EXHIBITS

Ex. 74	PDF – Philips USA's Website – Products Page – Features – DreamStation Go
Ex. 75	Environmental Protection Agency – Health and Environmental Effects of Particulate Matter
Ex. 76	Royal Philips Informational PDF – Sleep and Respiratory Care Update – Clinical Information for Physicians – updated 07/08/2021
Ex. 77	Philips Respironics – DreamStation Family Brochure
Ex. 78	[redacted]
Ex. 79	[redacted]
Ex. 80	[redacted]
Ex. 81	[redacted]
Ex. 82	[redacted]
Ex. 83	[redacted]
Ex. 84	[redacted]
Ex. 85	[redacted]
Ex. 86	[redacted]
Ex. 87	[redacted]
Ex. 88	[redacted]
Ex. 89	[redacted]
Ex. 90	[redacted]
Ex. 91	[redacted]
Ex. 92	[redacted]
Ex. 93	[redacted]
Ex. 94	Affidavit of Lee Lawler ("Lawler Affidavit"), Technical R&D Manager at Burnett – Filed in MDL No. 3014 – ECF No. 589-1 (Without Exhibits)

Ex. 95	Lawler Affidavit – Exhibit E – ECF No. 589-7 – Email exchange between Bob Marsh of PolyTech and Lee Lawler of Burnett
Ex. 96	[redacted]
Ex. 97	[redacted]
Ex. 98	Lawler Affidavit – Exhibit H – ECF No. 589-10 – Email Exchanges Between Philips and Supply Chain
Ex. 99	PDF – Polymer Technologies' Website – PE-PUR Foam Advertisement
Ex. 100	Lawler Affidavit – Exhibit I – ECF No. 598-11 – Additional Email Exchanges Between Philips and Supply Chain
Ex. 101	PDF – Philips Respironics' Website – Product Library
Ex. 102	PDF – Philips USA's Website – Sleep Therapy Solutions
Ex. 103	HME News – Business News For Home Medical Equipment Provides – dated 03/06/2020
Ex. 104	CPAP Direct – Products Page – SoClean Respironics System One & DreamStation Adapter
Ex. 105	DreamStation Humidifier User Manual
Ex. 106	Royal Philips Announces its 2021 First-Quarter Results – dated 04/26/2021
Ex. 107	Fair Disclosure Wire – Transcript of Royal Philips' 2021 First-Quarter Earnings Call – dated 04/26/2021
Ex. 108	Lawler Affidavit – Exhibit A – ECF No. 589-3 – RJ Lee Analysis of Trilogy Device Foam
Ex. 109	FDA – Recalls Background and Definitions Page
Ex. 110	PDF – ResMed's Website – Information regarding a separate manufacturer's product recall – dated 06/14/2021
Ex. 111	Royal Philips Press Release – Philips Provides Update on Philips Respironics PE-PUR Sound Abatement Foam Test and Research Program – dated 06/28/2022
Ex. 112	Philips' Test and Research Program for PE-PUR Foam
Ex. 113	Letter from Philips Defendants in MDL 3014 Regarding Initial Custodians – dated 09/15/2022
Ex. 114	LinkedIn Profile – Liz Iversen – Global EVP, Chief Quality & Regulatory Officer

Ex. 115	LinkedIn Profile – Carla Kriwet – Royal Philips CEO of Connected Care and Member of the Executive Committee
Ex. 116	Defendant Philips RS North America LLC's Initial Disclosures – dated 05/05/2022
Ex. 117	LinkedIn Profile – Thomas Catalano – Director of Products Marketing at Philips Respironics
Ex. 118	LinkedIn Profile – Francis Kim – EVP, Chief Quality & Regulatory Officer at Philips
Ex. 119	[redacted]
Ex. 120	LinkedIn Profile – Erin Levering – Medical Safety Manager at Philips
Ex. 121	LinkedIn Profile – Vitor Rocha – CEO of Philips North America
Ex. 122	LinkedIn Profile – Jessica Shen – Former Royal Philips SVP, Global Head of Medical Affairs, Clinical Affairs, HEOR & Regulatory Affairs
Ex. 123	Royal Philips 2022 First-Quarter Results Presentation
Ex. 124	Reuters – French Prosecutors Probe Philips Respirator Recall – dated 09/08/2022
Ex. 125	Royal Philips Press Release - Philips Provides Update on the Test and Research Program in Connection with the CPAP, BiPAP and Mechanical Ventilator Recall Notification – dated 12/23/2021
Ex. 126	Royal Philips Press Release – Philips Respironics Provides Update for the US on Ongoing CPAP, BiPAP and Mechanical Ventilator Field Action – dated 03/10/2022
Ex. 127	Royal Philips Press Release – Philips Provides Update on Filed MDRs in Connection with the Voluntary Recall Notification – dated 05/24/2022
Ex. 128	Philips Announces 2021 Second-Quarter Results – dated 07/26/2021
Ex. 129	Philips Announces 2021 Third-Quarter Results – dated 10/18/2021
Ex. 130	Philips Announces 2021 Fourth-Quarter and Annual Results – dated 01/24/2022
Ex. 131	Philips Announces 2022 Second-Quarter Results – dated 07/25/2022
Ex. 132	Philips 2021 Fourth-Quarter and Annual Results Presentation – dated 01/24/2022
Ex. 133	Fair Disclosure Wire – Transcript of Royal Philips Annual Shareholders Meeting – dated 05/10/2022

1. Plaintiffs, Drew Pendleton, Russell Autry, Deanna Melcher, Paul Bailey, Christine DiJohn, Patrick Nielson, Sylvia McDaniel, Jim Wolff, Jill Leavenworth, Jose Toscano, Jeffrey Boyle, Patricia Ragland, Tara Fields, Dennis Morris, Randy Paris, Brian McCarty, Michael Wheeler, Danny Baran, Debra Wilson, Michael Dusza, Steve Abarr, Sharon Cathers, Andrew Fisher, Doris Margoles, Wilbert Cotton, Quinton Goodall, Peter Bellotti, Prinna Boudreau, John Young, Danny David, Boniface Mills, Christopher Glaub, Elizabeth Lemus, Sabrina Malone, Aaron Taylor, Joe David Dennett, Beth Rodgers, Hugo Barragan, Sonia Diaz, Bruce Ginsberg, Jeffrey Bartalo, Deana King, Rachel Hock, Chad Wells, Arthur Hibbard, Joseph Hoffman, Marilyn Sweeney, Antonio Perez Bonano, Diane Lamontagne, Stephen Flannery, Susan Bakaitis, Jeffrey Kemp, Sarah Claunch, Paul Panzera, Martin Humphries, David Martin, Madaline Harbor, Elizabeth Heilman, Cameron Rose, Jose Lopez, Robert Peebles, Dennis Caling, and Brent Hamlin ("Plaintiffs" or "Medical Monitoring Class Plaintiffs"), individually and on behalf of all others similarly situated, through the undersigned counsel, allege as follows:

2. The Medical Monitoring Class Plaintiffs file this Consolidated Second Amended Class Action Complaint for Medical Monitoring and Demand for Jury Trial ("Medical Monitoring Class Complaint" or "Complaint") against Defendants Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., Philips RS North America LLC, Philips RS North America Holding Corporation, Polymer Technologies, Inc., and Polymer Molded Products LLC (collectively, "Defendants"), bringing claims of, among other things, negligence, strict liability, medical monitoring, fraudulent and negligent misrepresentations and omissions, and breach of express and implied warranties.

3. Pretrial Order #14 ("PTO 14") (ECF 573), set forth an orderly and efficient process for filing Consolidated Amended Class and Master Complaints. Pursuant to PTO 14, a Medical

Monitoring Class Complaint is one of three master complaints being filed in this multi-district litigation. The Consolidated Amended Class Action Complaint for Medical Monitoring was filed on August 22, 2022 (ECF 694), and a deadline for filing a Consolidated Second Amended Class Action Complaint for Medical Monitoring was set for October 17, 2022 (ECF 768). The filing of three separate master complaints is only to streamline the issues within each of the pleadings for the mutual convenience of both the Court and the parties. Medical Monitoring Class Plaintiffs do not waive any claims that are not asserted here, or that are asserted in one of the other master complaints. *See, e.g.*, Consolidated Third Amended Class Action Complaint for Economic Losses (ECF 785) ("Economic Loss Complaint"); Amended Master Long Form Complaint for Personal Injuries and Damages, and Demand for Jury Trial (to be filed October 24, 2022) ("Master PI Complaint").

I. NATURE OF THE ACTION

4. Defendant Koninklijke Philips N.V. ("Royal Philips") is a Dutch multinational company that is the global head of the "Philips" enterprise, which bills itself as "a diverse team made up of some 80,000 individuals across over 100 countries, all with different backgrounds, perspectives and experiences."[1] Royal Philips controls and oversees all aspects of the Philips businesses around the world, going to great lengths to ensure there is a unity of purpose and vision, consistent execution of company procedures, policies, and goals, and, importantly, maintenance and protection of the valuable "Philips" brand. In addition to Royal Philips, Defendants Philips North America LLC ("Philips NA"), Philips Holding USA Inc. ("Philips USA"), Philips RS North America LLC ("Philips RS"), and Philips RS North America Holding Corporation ("Philips RS

[1] *See* Royal Philips "About us" webpage, https://www.philips.com/a-w/about.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "1"). All attached Exhibits and reference material are incorporated as if fully stated herein.

Holding") are essential parts of the Philips family that, along with other Philips' entities, engaged in the wrongful conduct at issue in this litigation. These Defendants are referred to collectively herein as "Philips" or the "Philips Defendants." At all relevant times, each Philips Defendant acted in all aspects as the agent and alter ego of one another, and references to "Philips" refer to each Philips Defendant individually and collectively.

5. Royal Philips boasts on its website, www.philips.com[2]: "Over the past decade we have transformed into a focused leader in health technology…. At Philips, our purpose is to improve people's health and well-being through meaningful innovation."[3] As part of that business, Philips manufactures and sells certain lines of products that are intended to help people breathe. These include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, which are commonly used to treat sleep apnea, and mechanical ventilators ("ventilators"), which treat respiratory failure. The primary function of these devices is to blow air into patients' airways. CPAP and BiPAP machines are intended for use during sleep while ventilators are used continuously when needed.

6. Because these machines are used during sleep, Philips designed them to include sound-dampening foam intended to reduce noise emitted from the motors in the devices. Unfortunately, Philips designed its devices to include polyester-based polyurethane ("PE-PUR") foam, which Philips knew for many years, among other things, is susceptible to hydrolysis, the

[2] The landing (*i.e.*, opening) page for Royal Philips' website contains a copyright for Royal Philips. *See* https://www.philips.com/global ("© Koninklijke Philips N.V., 2004 - 2022. All rights reserved.") (last accessed Oct. 3, 2022) (attached hereto as Exhibit "2"). When accessing the Royal Philips website from the United States, users are automatically redirected to https://www.usa.philips.com/ (last accessed Oct. 3, 2022). The redirected page also contains a copyright for Royal Philips. *See* https://www.usa.philips.com/ ("© Koninklijke Philips N.V., 2004 - 2022. All rights reserved.") (last accessed Oct. 3, 2022) (attached hereto as Exhibit "3").

[3] Royal Philips "About us" webpage (Exhibit "1" hereto).

chemical breakdown of a compound due to reaction with water, particularly in medical applications. This can result in degradation of the foam and off-gassing of volatile organic compounds ("VOCs").

7. On June 14, 2021, Philips, through multiple of its entities, including Royal Philips and Philips RS, announced a recall of approximately 11 million of its CPAP and BiPAP machines and ventilators in the United States that were manufactured with PE-PUR foam from 2008 until the date of the recall (the "Recall"). All of these recalled products (individually referred to herein as a "Recalled Device," or collectively, as the "Recalled Devices") are defective because they contain PE-PUR foam.

8. The Recalled Devices are:

- E30
- DreamStation ASV
- DreamStation ST, AVAPS
- SystemOne ASV4
- C Series ASV, S/T, AVAPs
- OmniLab Advanced Plus
- SystemOne (Q Series)
- DreamStation CPAP, Auto CPAP, BiPAP
- DreamStation Go CPAP, APAP
- Dorma 400, 500 CPAP
- REMStar SE Auto CPAP
- Trilogy 100 and 200
- Garbin Plus, Aeris, LifeVent

- A-Series BiPAP Hybrid A30
- A-Series BiPAP V30 Auto
- A-Series BiPAP A40
- A-Series BiPAP A30

9. The use of PE-PUR foam in the Recalled Devices is a defect because the foam is susceptible to breaking down into particles which may then be inhaled or ingested by the user, and may emit VOCs that can also be inhaled, resulting in "serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."[4]

10. Philips was aware of problems with the PE-PUR foam in the Recalled Devices dating as far back as 2008 when it began receiving numerous complaints from customers including complaints containing the keywords "contaminants, particles, foam, debris, airway, particulate, airpath, and black."[5] In addition, beginning as far back as 2015, Philips conducted and received multiple test reports and additional data confirming that the Recalled Devices pose serious, indeed life-threatening, health risks to users, but Philips failed to timely disclose that they were defective when manufactured and sold.

[4] Philips Recall Notices issued June 14, 2021 (attached hereto as Exhibit "4").

[5] *See* FDA 483 Report issued to Philips on November 9, 2021 (hereinafter "483 Report"), redacted version available at: https://www.fda.gov/media/154244/download (last accessed Oct. 3, 2022) (attached hereto as Exhibit "5"), at 12. A 483 Report from the Food and Drug Administration ("FDA") "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts." FDA webpage, FDA Form 483 Frequently Asked Questions, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last accessed Oct. 3, 2022) (attached hereto as Exhibit "6").

11. Instead of instituting a recall immediately, Philips waited until June 2021 to issue the Recall and notify the public about the dangers of the Recalled Devices, continuing to sell defective devices and leaving users to breathe in the toxic fumes and risk serious injury. In its Recall, Philips publicly announced that the PE-PUR foam may break down into particles and be inhaled or ingested, and may emit VOCs that can be inhaled, resulting in "serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment"[6] (referred to herein as the "Defect"). Philips stated that the potential risks of exposure due to such chemicals include "headache/dizziness, irritation (eyes, nose respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects."[7] Philips' announcement to doctors advised that these hazards could result in "serious injury which can be life-threatening or cause permanent impairment."[8]

12. In addition, on July 22, 2021, the U.S. Food and Drug Administration ("FDA") confirmed the severity of the issues described in the Recall and classified the Recall as Class I or "the most serious type of recall," meaning use of the Recalled Devices "may cause serious injuries or death."[9]

13. As noted above, Philips knew about the serious risks caused by the Recalled Devices long before the Recall.

---

[6] Philips Recall Notices issued June 14, 2021 (Exhibit "4" hereto).

[7] *Id*.

[8] *See* Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical information for physicians (June 14, 2021), at 2, available at: philips-recall-clinical-information-for-physicians-and-providers.pdf (last accessed Oct. 3, 2022) (attached hereto as Exhibit "7").

[9] FDA Notice, "Philips Respironics Recalls Certain Continuous and Non-Continuous Ventilators, including CPAP and BiPAP, Due to Risk of Exposure to Debris and Chemicals," available at: https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and (last accessed Oct. 3, 2022) (attached hereto as Exhibit "8").

14. On November 9, 2021, the FDA issued a report detailing the findings of an FDA investigation, findings that demonstrate Philips knew that the PE-PUR foam degraded into hazardous substances.[10] The FDA discovered emails, dating back to October 2015, to Philips from the supplier of the raw foam used to make the PE-PUR foam in the Recalled Devices regarding PE-PUR foam degradation issues.[11] Additionally, the FDA found that, in November 2015, Philips engaged in preventative maintenance on certain Recalled Devices in response to PE-PUR foam degradation issues and complaints, yet failed to conduct any "further investigation, health hazard evaluation, risk analysis, or design review" on any of the Recalled Devices that use the same PE-PUR foam.[12] To be sure, the FDA found that "there were at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions."[13] This is in addition to the detailed customer complaints that existed as far back as 2008 and the additional data Philips collected in 2015.

15. Despite knowing about the degradation and off-gassing problems with the PE-PUR foam and the associated health risks for users of the affected devices, Philips failed until many years later to disclose the Defect to consumers, hospitals, institutions, doctors, and suppliers, continuing to sell the defective products and allowing patients to use the defective products. In addition, Defendant Polymer Technologies, Inc. ("PolyTech"), a supplier of PE-PUR foam to Philips, worked with Philips to conceal these key facts from consumers so that both could continue to profit from the sales of these defective devices.

---

[10] *See generally*, 483 Report (Exhibit "5" hereto).

[11] *Id*. at 3, 18.

[12] *Id*. at 2.

[13] *Id*. at 3.

16. It was only after Philips launched its next generation of CPAP/BiPAP machines (the DreamStation 2 devices), machines that do not contain PE-PUR foam and could serve as a replacement for Recalled Devices, that Philips finally disclosed that its Recalled Devices were defective. That is, on April 26, 2021, Philips announced that its previous generation DreamStation products and other CPAP, BiPAP, and ventilator devices posed serious health risks to users. Philips then waited an additional seven weeks before initiating the Recall of the dangerously defective machines in the United States. Shortly thereafter, Philips expanded its recall of defective CPAP, BiPAP, and ventilator devices worldwide.[14]

17. Because of the increased demand for safe and effective CPAP, BiPAP, and ventilator devices at the time of the Recall, replacement machines were difficult to find and expensive, a situation that was exacerbated by a shortage of microchips for these devices. Thus, many users were forced into a Hobson's choice – continue using their Recalled Devices and expose themselves to risks of serious injury or death or stop using their breathing devices and risk health consequences from their underlying conditions.

18. When the Recall was first announced on June 14, 2021, Philips did not offer users of the Recalled Devices any option for a replacement device.

[14] *See, e.g.*, Philips website, Urgent Product Defect Correction in Australia (Recall for Product Correction in New Zealand), https://www.philips.com.au/healthcare/e/sleep/communications/src-update (last accessed Oct. 3, 2022) (attached hereto as Exhibit "9") (stating that a global recall notification was issued on June 14, 2021 and that recalls specific to Australia and New Zealand were issued on July 2, 2021). As discussed, *infra*, in note 368, other impacted countries include, but are not limited to Canada, Israel, and Chile.

19. On September 1, 2021, Philips received authorization from the FDA to begin a repair and/or replacement process for affected DreamStation devices in the United States, and initially, Philips estimated that it would take a year to complete the program.[15]

20. In announcing the repair/replacement program, Royal Philips CEO Frans van Houten acknowledged that patients using Recalled Devices needed a solution and that delayed relief for them presented a problem: "We fully recognize that the timeframe for remediation of the affected devices places patients in a difficult situation."[16]

21. Unfortunately for users of the recalled DreamStation devices, the repair and replacement program was negligently implemented and ineffective. DreamStation customers were not given any specifics as to how the replacement program would work nor were they told when they might receive a replacement device (a significant factor for users who relied on the machines for medical conditions). Nor did Philips provide meaningful guidance to DreamStation customers' treating physicians. In addition, the repair and/or replacement program was limited in that it only impacted DreamStation Recalled Devices and not any other Recalled Device.

22. Each of the Plaintiffs has used a Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged

[15] *See* Royal Philips Press Release, Philips starts repair and/or replacement program of first-generation DreamStation devices in the US and other markets (Sept. 1, 2021), https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210901-philips-starts-repair-and-replacement-program-of-first-generation-dreamstation-devices-in-the-us-in-relation-to-earlier-announced-recall-notification.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "10"); *see also* Philips "Ventilation News and Updates" webpage, Trilogy Remediation Update for Business Customers (June 1, 2022), https://www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/ventilation-news-and-updates (last accessed Oct. 7, 2022) (attached hereto as Exhibit "11").

[16] *Id*.

herein. Had Plaintiffs known that the Recalled Device would cause exposure to dangerous toxins, they would not have used it.

23. Plaintiffs, individually and on behalf of all others similarly situated, seek to recover economic losses for the costs of a program of medical monitoring and punitive damages from Philips for breach of express warranty, breach of the implied warranty of merchantability, breach of the implied warranty of usability, the Magnuson Moss Warranty Act, fraud, the Racketeer Influenced and Corrupt Organizations ("RICO") Act, negligent failure to recall/negligent recall, unjust enrichment, redhibition, and applicable state consumer protection statutes.[17] Plaintiffs in this Medical Monitoring Class Complaint do not seek the costs of, or replacement or repair of, the Recalled Devices.

II. THE PARTIES

A. PLAINTIFFS

24. As noted above, there are three master complaints contemplated in this MDL divided, for administrative purposes, into one each for Personal Injury, Medical Monitoring, and Economic Loss. Medical Monitoring Class Plaintiffs identified below are also members of the putative class in the Economic Loss Complaint, and do not waive any of their rights or claims as putative class members in that complaint by virtue of serving as proposed Class Representatives for the class or classes proposed in this Medical Monitoring Class Complaint. Furthermore, the parties identified below as Medical Monitoring Class Plaintiffs, in filing this Medical Monitoring Class Complaint, which is limited to compensation for the cost of medical monitoring per the administrative structure, do not waive, forego, or otherwise relinquish any entitlement they have

[17] Plaintiffs reserve the right to amend this Complaint to reflect additional information uncovered through discovery and developed *via* expert testimony.

to economic remedies for all harms incurred as a result of Philips' misconduct and preserve their entitlement to all relief available for the harms alleged.

25. The Medical Monitoring Class Plaintiffs are individuals, each of whom used the Recalled Devices and have suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases from this use.

26. Plaintiff Drew Pendleton ("Pendleton") is a resident of Arizona. Plaintiff acquired a Philips REMStar on or about February 2015, in Washington. Since acquiring the device, Plaintiff has lived in Idaho, Utah, and Arizona. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

27. Plaintiff Russell Autry ("Autry") is a resident of Arkansas. Plaintiff acquired a Philips Respironics DreamStation Auto CPAP on or about December 2019, in Arkansas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

28. Plaintiff Deanna Melcher ("Melcher") is a resident of Arkansas. Plaintiff acquired a Philips DreamStation on or about March 2020, in Arkansas. Plaintiff has used the Recalled

Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

29. Plaintiff Paul Bailey ("Bailey") is a resident of California. Plaintiff acquired a Philips DreamStation Auto BiPAP on or about October 2018, in California. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

30. Plaintiff Christine DiJohn ("DiJohn") is a resident of California. Plaintiff acquired a Philips DreamStation on or about September 2008, in California. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

31. Plaintiff Patrick Nielson ("Nielson") is a resident of California. Since acquiring the device, plaintiff has lived in Oregon and California since acquiring the Recalled Devices. Plaintiff acquired a Philips Respironics PR System One REMstar PRO in or about March 2014, in California Plaintiff later acquired another Philips Respironics PR System One REMstar PRO in or

about May 2016, in Oregon. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

32. Plaintiff Sylvia McDaniel ("McDaniel") is a resident of Colorado. Plaintiff acquired a Philips DreamStation on or about August 2019, in Colorado. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

33. Plaintiff Jim Wolff ("Wolff") is a resident of Colorado. Plaintiff acquired a Philips DreamStation on or about February 2020, in Colorado. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

34. Plaintiff Jill Leavenworth ("Leavenworth") is a resident of Connecticut. Plaintiff acquired a Philips DreamStation on or about May 2020, in Connecticut. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently

suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

35. Plaintiff Jose Toscano ("Toscano") is a resident of Connecticut. Plaintiff acquired a Philips DreamStation on or about November 2016, and a second Philips DreamStation on or about November 2020, in Connecticut. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged here. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

36. Plaintiff Jeffrey Boyle ("Boyle") is a resident of Delaware. Plaintiff acquired a Philips DreamStation on or about 2016, in Delaware. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

37. Plaintiff Patricia Ragland ("Ragland") is a resident of the District of Columbia. Plaintiff acquired a Philips REMstar on or about 2012, in the District of Columbia. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's

exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

38. Plaintiff Tara Fields ("Fields") is a resident of Florida. Plaintiff acquired and used a Philips REMStar CPAP in or around July 2020 in Florida. She used the REMStar until she acquired a Philips DreamStation CPAP on or about September 2020, which she used until at least the date of the Recall. As a result of using the Recalled Devices, Plaintiff suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, she would not have used them.

39. Plaintiff Dennis Morris ("Morris") is a resident of Florida. Plaintiff acquired a Philips DreamStation CPAP on or about November 2018 in Florida. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

40. Plaintiff Randy Paris ("Paris") is a resident of Florida. Plaintiff acquired a Philips DreamStation CPAP on or about July 2016, in Florida. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins,

Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

41. Plaintiff Brian McCarty ("McCarty") is a resident of Hawaii and has lived in Hawaii and Illinois since acquiring the Recalled Devices. Plaintiff has acquired and used three Recalled Devices until at least the date of the Recall. Plaintiff acquired a Philips DreamStation CPAP on or about August 2015 for use in Hawaii, a Philips DreamStation CPAP on or about November 2016, for use in Illinois, and a Philips DreamStation Go on or about November 2016 for use during travel. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

42. Plaintiff Michael Wheeler ("Wheeler") is a resident of Idaho. Plaintiff acquired a Philips DreamStation CPAP on or about December 2018, in Idaho. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

43. Plaintiff Danny Baran ("Baran") is a resident of Illinois. Plaintiff acquired a Philips DreamStation Auto CPAP in or about February 2019, in Illinois. Plaintiff has used the Recalled

Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

44. Plaintiff Debra Wilson ("Wilson") is a resident of Illinois. Plaintiff acquired a Philips DreamStation on or about June 2019, in Illinois. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

45. Plaintiff Michael Dusza ("Dusza") is a resident of Indiana. Plaintiff acquired a Philips DreamStation CPAP on or about June 2016, in Indiana. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

46. Plaintiff Steve Abarr ("Abarr") is a resident of Iowa. Plaintiff acquired a Philips SystemOne on or about March 2015 and a Philips DreamStation Auto BiPAP on or about December 2019, in Iowa. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged

herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

47. Plaintiff Sharon Cathers ("Cathers") is a resident of Kansas. Plaintiff acquired a Philips DreamStation on or about January 2021, in Kansas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

48. Plaintiff Andrew Fisher ("Fisher") is a resident of Georgia. Since acquiring the device, Plaintiff has lived in Kansas and Georgia. Plaintiff acquired a Philips DreamStation on or about April 2020 in Missouri, while residing in Kansas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

49. Plaintiff Doris Margoles ("Margoles") acquired a Philips DreamStation Auto CPAP on or about October 2017 when she resided in Maine. Since 2017, Plaintiff has also lived in North Carolina and recently moved to Ohio. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to

dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

50. Plaintiff Wilbert Cotton ("Cotton") is a resident of Maryland. Plaintiff acquired a Philips DreamStation on or about March 2020 in Maryland. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

51. Plaintiff Quinton Goodall ("Goodall") is a resident of Maryland. Plaintiff acquired a Philips DreamStation on or about August 2016, in Maryland. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

52. Plaintiff Peter Bellotti ("Bellotti") is a resident of Massachusetts. Plaintiff acquired a DreamStation Auto CPAP on or about September 2017, in Massachusetts. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create

and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

53. Plaintiff Prinna Boudreau ("Boudreau") is a resident of Minnesota. Plaintiff acquired a Philips DreamStation on or about 2011, and a Philips System One BiPAP Auto on or about 2019 or 2020, both in Minnesota. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, she would not have used them.

54. Plaintiff John Young ("Young") is a resident of Missouri. Plaintiff acquired a SystemOne in or about August 2013, and a DreamStation in or about January 2021, both in Missouri. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

55. Plaintiff Danny David ("David") is a resident of Montana. Plaintiff acquired a Philips DreamStation Auto CPAP on or about January 2021, in Montana. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create

and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

56. Plaintiff Boniface Mills ("Mills") is a resident of Nebraska. Plaintiff acquired a DreamStation in or around 2015, in Nebraska. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

57. Plaintiff Christopher Glaub ("Glaub") is a resident of Nebraska. Plaintiff acquired a REMStar Pro in or about 2013, in Nebraska. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

58. Plaintiff Elizabeth Lemus ("Lemus") is a resident of Nevada. Plaintiff acquired a DreamStation Auto CPAP in or about September 2017, in Nevada. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

59. Plaintiff Sabrina Malone ("Malone") is a resident of New Hampshire. Since acquiring the device, plaintiff has lived in Texas and New Hampshire. Plaintiff acquired a Philips Respironics DreamStation Auto CPAP on or about January 2018, in Texas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

60. Plaintiff Aaron Taylor ("Taylor") is a resident of New Jersey. Plaintiff acquired a Philips DreamStation Respironics REMstar Pro C-Flex+ System One in or around 2007 or 2008 and a DreamStation CPAP Pro Hum Cell DOM in or around 2015, in New Jersey. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

61. Plaintiff Joe David Dennett ("Dennett") is a resident of New Mexico. Plaintiff acquired a Philips DreamStation on or about September 2019 in New Mexico. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases.

Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

62. Plaintiff Beth Rodgers ("Rodgers") is a resident of Virginia. Since acquiring her devices, Plaintiff has resided in Virginia and New Mexico. Plaintiff acquired a SystemOne in or about 2013, in New Mexico, and later acquired a DreamStation in or about June 2019, in Virginia. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, she would not have used them.

63. Plaintiff Hugo Barragan ("Barragan") is a resident of New York. Plaintiff acquired a DreamStation in or about October 2020, in New York. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

64. Plaintiff Sonia Diaz ("Diaz") has resided in New York and South Carolina since acquiring her Recalled Device. Plaintiff acquired a Philips DreamStation Auto CPAP in or about October 2016 in New York. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered

subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

65. Plaintiff Bruce Ginsberg ("Ginsberg") is a resident of New York. Plaintiff acquired a Philips DreamStation CPAP on or about 2018, in New York. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

66. Plaintiff Jeffrey Bartalo ("Bartalo") is a resident of North Carolina. Plaintiff acquired a Philips DreamStation in or about December 2019, in North Carolina. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

67. Plaintiff Deana King ("King") is a resident of North Carolina. Plaintiff acquired a DreamStation Auto BiPAP in or about April 2016, in North Carolina. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create

and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

68. Plaintiff Rachel Hock ("Hock") is a resident of Ohio. Plaintiff acquired a Philips System One REMstar 50 Series on or about 2014, and a Philips DreamStation Auto CPAP on or about November 2018, both in Ohio. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, she would not have used them.

69. Plaintiff Chad Wells ("Wells") is a resident of Oklahoma. Plaintiff acquired a Philips SystemOne BiPAP/BiFLEX in or about August 2012, in Oklahoma. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

70. Plaintiff Arthur Hibbard ("Hibbard") is a resident of Pennsylvania. Plaintiff acquired Philips REMStar devices beginning in or about 2008, and continued to use them through 2021. Plaintiff later acquired a Philips DreamStation in or about March 2021. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological

changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

71. Plaintiff Joseph Hoffman ("Hoffman") is a resident of Pennsylvania. Plaintiff acquired a Philips REMStar in or about October 2015, in Pennsylvania. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

72. Plaintiff Marilyn Sweeney ("Sweeney") is a resident of Pennsylvania. Plaintiff acquired a Philips DreamStation Auto CPAP HTWifi DOM on or about February 1, 2019, and a Philips DreamStation Go Auto CPAP on or about February 12, 2019, in Pennsylvania. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, she would not have used them.

73. Plaintiff Antonio Perez Bonano ("Bonano") is a resident of Puerto Rico. Plaintiff acquired a Philips DreamStation Auto CPAP in or about April 2019, in Puerto Rico. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged. As a result of Plaintiff's exposure

to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

74. Plaintiff Diane Lamontagne ("Lamontagne") is a resident of Rhode Island. Plaintiff acquired a Philips DreamStation Auto CPAP in or about March 2016, in Rhode Island. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

75. Plaintiff Stephen Flannery ("Flannery") is a resident of South Carolina. Plaintiff acquired a DreamStation on or about February 2018, in South Carolina. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

76. Plaintiff Susan Bakaitis ("Bakaitis") is a resident of Tennessee. Plaintiff acquired a Philips DreamStation CPAP on or about December 2020 in Tennessee. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these

dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

77. Plaintiff Jeffrey Kemp ("Kemp") is a resident of Tennessee. Plaintiff acquired a Philips DreamStation Auto CPAP in or about 2017, in Tennessee. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

78. Plaintiff Sarah Claunch ("Claunch") is a resident of Texas. Plaintiff acquired a Philips DreamStation CPAP on or about September 2018, in Texas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

79. Plaintiff Paul Panzera ("Panzera") is a resident of Texas. Plaintiff acquired a Philips DreamStation Auto CPAP in or about August 2018, in Texas. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create

and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

80. Plaintiff Martin Humphries ("Humphries") is a resident of Utah. Plaintiff acquired a Philips SystemOne ASV4 in or about 2014, in Utah. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

81. Plaintiff David Martin ("Martin") is a resident of Vermont. Plaintiff acquired a Philips REMStar Auto BiPAP in or about 2011, and a Philips DreamStation Auto BiPAP in or about 2017, in Vermont. Plaintiff has used the Recalled Devices since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Devices would cause exposure to dangerous toxins, he would not have used them.

82. Plaintiff Madaline Harbor ("Harbor") is a resident of Virginia. Plaintiff acquired a Philips DreamStation on or about August 2016, in Virginia. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the

risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

83. Plaintiff Elizabeth Heilman ("Heilman") is a resident of Virginia. Plaintiff acquired a Philips DreamStation in or about 2018, in Virginia. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, she would not have used it.

84. Plaintiff Cameron Rose ("Rose") is a resident of Virginia. Plaintiff acquired a Philips DreamStation Auto CPAP on or about April 2018, in Virginia. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

85. Plaintiff Jose Lopez ("Lopez") is a resident of Washington. Plaintiff acquired a Philips DreamStation Auto CPAP on or about December 2018 or January 2019, in Washington. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and

other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

86. Plaintiff Robert Peebles ("Peebles") is a resident of Washington. Plaintiff acquired a Philips DreamStation in or about October 2020, in Washington. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

87. Plaintiff Dennis Caling ("Caling") is a resident of West Virginia. Plaintiff acquired a Philips DreamStation CPAP on or about July 2019, in West Virginia. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

88. Plaintiff Brent Hamlin ("Hamlin") is a resident of West Virginia. Plaintiff acquired a Philips Respironics DreamStation Auto CPAP in or about December 2019, in West Virginia. Plaintiff has used the Recalled Device since the time of acquisition until at least the date of the Recall and consequently suffered exposure to dangerous toxins as alleged herein. As a result of Plaintiff's exposure to these dangerous toxins, Plaintiff suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and

other diseases. Had Plaintiff known that the Recalled Device would cause exposure to dangerous toxins, he would not have used it.

B. DEFENDANTS

89. Defendant Royal Philips is a Dutch multinational publicly traded company having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the ultimate parent company of the Philips Group of healthcare technology businesses including Connected Care businesses focusing on Sleep & Respiratory Care.[18] "The Company, which started as a limited partnership with the name Philips & Co in Eindhoven, the Netherlands, in 1891, was converted into the company with limited liability N.V. Philips' Gloeilampenfabrieken on September 11, 1912. The Company's name was changed to Philips Electronics N.V. on May 6, 1994, and then to Koninklijke Philips Electronics N.V. on April 1, 1998, and [finally] to Koninklijke Philips N.V. on May 15, 2013."[19] Royal Philips' shares have been listed on the Amsterdam stock exchange since 1912, have been traded in the United States since 1962, and have been listed on the New York Stock exchange since 1987.[20] Royal Philips holds directly or indirectly 100% of its subsidiaries, Philips NA, Philips USA, Philips RS

[18] Royal Philips Press Release, Philips realigns the composition of its reporting segments (Jan. 10, 2019), https://www.philips.com/a-w/about/news/archive/standard/news/press/2019/20190110-philips-realigns-the-composition-of-its-reporting-segments.html (last accessed Oct. 8, 2022) (attached hereto as Exhibit "137").

[19] Royal Philips 2017 Annual Report (attached hereto as Exhibit "12"), at 84. Note all quarterly and annual reports and SEC 20-F filings from 2009 to the present can be found at this link, under the "All Results" tab: https://www.results.philips.com/publications/ar21 (last accessed Oct. 3, 2022).

[20] *Id.*; *see also* Royal Philips 2021 Annual Report, available for download at https://www.results.philips.com/publications/ar21 (last accessed Oct. 3, 2022) (attached hereto as Exhibit "13"), at 117.

Holding, and Philips RS.[21] As such, Royal Philips controls Philips NA and Philips RS with respect to the manufacturing, selling, distributing, and supplying of the Recalled Devices.[22]

90. Defendant Philips NA is a Delaware company that was incorporated on August 6, 1987,[23] having its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA was "formerly known as Philips Electronics North America Corporation."[24] Philips NA is a wholly-owned subsidiary of Royal Philips, managed by Philips USA.[25]

[21] Royal Philips 2021 SEC Form 20-F filing, Exhibit 8, List of Subsidiaries, available at: https://www.sec.gov/Archives/edgar/data/313216/000031321622000008/phg-exhibit8.htm (last accessed Oct. 3, 2022) (attached hereto as Exhibit "14"). In its 2019 SEC Form 20-F filing, Exhibit 8, Royal Philips also lists Respironics, Inc. as a wholly-owned subsidiary (attached hereto as Exhibit "15"). However, Respironics, Inc. is no longer listed as a subsidiary on Royal Philips 2020 SEC Form 20-F filing, Exhibit 8, available at: https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm (last accessed Oct. 3, 2022) (attached hereto as Exhibit "16"); rather, Royal Philips lists Philips RS North America LLC as a subsidiary. *Id.*

[22] *See* Royal Philips 2020 SEC Form 20-F filing, Exhibit 8 (Exhibit "16" hereto).

[23] State of Delaware, Dept. of State, Div. of Corporations, Entity Details of Philips North America LLC (attached hereto as Exhibit "17").

[24] *See* Complaint for Patent Infringement in *Koninklijke Philips N.V., et al. v. Meditek, Inc., et al.*, No. 1:20-cv-01246-UNA, ECF No. 1, (D. Del. Sept. 17, 2020) (attached hereto as Exhibit "18"). "Philips Electronics North America Corporation" is listed as a subsidiary of Royal Philips as of its 2016 Annual Report, Exhibit 8, List of Subsidiaries (attached hereto as Exhibit "19"). "Philips North America LLC" is not listed therein. *Id.* However, "Philips North America LLC" is listed as a subsidiary of Royal Philips on the 2017 SEC 20-F filing, Exhibit 8, List of Subsidiaries, available at: https://www.sec.gov/Archives/edgar/data/313216/000119312517050359/d330553d20f.htm (last accessed Oct. 4, 2022) (attached hereto as Exhibit "20").

[25] Corporate Disclosure Statement in *Newsome, Jr., et al. v. Philips North America LLC, Koninklijke Philips N.V., Philips RS North America LLC, Respironics, Inc., et al.*, 4:22-cv-04101-HSG (N.D. Cal. July 13, 2022), ECF No. 2 ("Newsome Corp. Discl. Stmt.") (attached hereto as Exhibit "21").

91. Defendant Philips USA is a Delaware corporation that was incorporated on July 18, 1995,[26] having its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips USA is a holding company that is 100% owned, directly or indirectly, by Royal Philips. Philips USA manages the operations of Royal Philips' various lines of business including Philips RS Holding and through it, Philips RS.[27] Philips USA is also the member/manager of Philips NA.[28]

92. Defendant Philips RS is a Delaware company that was incorporated on February 22, 1984,[29] having its principal place of business at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is 100% owned by Philips RS Holding, which in turn, is 100% owned by Philips USA.[30] Philips RS formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008,[31] creating "Philips Respironics."[32] However, "Philips

[26] State of Delaware, Dept. of State, Div. of Corporations, Entity Details of Philips Holding USA Inc. (attached hereto as Exhibit "22").

[27] Newsome Corp. Discl. Stmt. (Exhibit "21" hereto).

[28] *Id.*

[29] State of Delaware, Dept. of State, Div. of Corporations, Entity Details of Philips RS North America LLC (attached hereto as Exhibit "23").

[30] *See* Newsome Corp. Discl. Stmt. (Exhibit "21" hereto); *see also, e.g.*, State of Mississippi, Secretary of State, certificate for Philips RS North America LLC (Respironics, Inc.), which lists that it is a "Member" of Philips RS North America Holding Corporation. This certificate also states an "intent to dissolve" with an effective date of "04/05/2017" (attached hereto as Exhibit "24").

[31] Philips announces completion of tender offer to acquire Respironics, WebWire (Mar. 14, 2008), https://www.webwire.com/ViewPressRel.asp?aId=61199 (last accessed Oct. 3, 2022) (attached hereto as Exhibit "25").

[32] *See History of BiPAP – Respironics and Philips Respironics, cpap.com, last updated* (Dec. 9, 2021), https://www.cpap.com/blog/history-bipap-respironics-philips/ (last accessed Oct. 3, 2022) (attached hereto as Exhibit "26"); *see also* Philips in $5 billion Respironics deal, Reuters (Dec. 21, 2007), https://www.reuters.com/article/us-philips/philips-in-5-billion-respironics-deal-idUSL2131786820071221 (last accessed Oct. 3, 2022) (attached hereto as Exhibit "27"); *see also* Philips makes $5.1B public offer to acquire Respironics, ReliablePlant (undated),

Respironics is a fictitious name that is 100% owned by Philips RS [N]orth America LLC."[33] In October 2020, shortly before the Recall, Respironics, Inc. was newly registered under the name Philips RS North America, LLC.[34]

93. Defendant Philips RS Holding is a Delaware corporation that was incorporated on October 31, 2020,[35] having its principal place of business at 222 Jacobs Street, Cambridge, Massachusetts 02141, and is wholly owned by Philips USA. Accordingly, Philips RS Holding is a citizen of Massachusetts and Delaware.

94. At all relevant times, each Philips Defendant acted in all aspects as the agent and alter ego of one another, and reference to "Philips" refers to each Philips Defendant individually and collectively.

95. Defendant Polymer Technologies, Inc. ("PolyTech") is a Delaware corporation with its principal place of business at 420 Corporate Boulevard, Newark, Delaware 19702.

---

https://www.reliableplant.com/Read/9713/philips-makes-$51b-public-offer-to-acquire-respironics (last accessed Oct. 3, 2022) (attached hereto as Exhibit "28").

[33] Newsome Corp. Discl. Stmt. (Exhibit "21" hereto). Yet, Philips Respironics has a dedicated webpage which states, "About Philips Respironics – As a global leader in the sleep and respiratory markets, we're passionate about providing solutions that lead to healthier patients, practices, and businesses." *See* http://www.respironics.com/Philips (last accessed Oct. 3, 2022) (attached hereto as Exhibit "29"). Royal Philips holds the copyright on this webpage as of "2004 – 2022" with "[a]ll rights reserved." *Id.* The webpage has a link to a "Privacy policy" that is titled "Philips Privacy Notice" that states "the controller of your personal data (as well as the controller's representative in the European Union) is Philips International B.V. *Id.* Philips International B.V. was founded in 1994. *See Bloomberg* profile for Philips International B.V., https://www.bloomberg.com/profile/company/1071145D:NA (last accessed Oct. 5. 2022) (attached hereto as Exhibit "141"). Philips International B.V. is a wholly-owned subsidiary of Royal Philips. Royal Philips 2021 SEC Form 20-F filing, Exhibit 8, List of Subsidiaries (Exhibit "14" hereto).

[34] State of Delaware Certificate of Conversion (Nov. 9, 2020) (attached hereto as Exhibit "30").

[35] State of Delaware, Dept. of State, Div. of Corporations, Entity Details of Philips RS North America Holding Corporation (attached hereto as Exhibit "31").

PolyTech directly or through another intermediary provided Philips with the PE-PUR foam that was used in the Recalled Devices.

96. Defendant Polymer Molded Products LLC ("PMP") is a Delaware corporation with its principal place of business at 10 Easy Street, Bound Brook, NJ 08805. PMP is a molded polyurethane foam manufacturer. PMP directly or through another intermediary provided Philips with the PE-PUR foam that was used in the Recalled Devices.

97. At all relevant times, Defendants PolyTech and PMP acted in all respects as the agent and alter ego of one another, and reference hereinafter to "PolyTech" or the "PolyTech Defendants" refers to Defendants PolyTech and PMP individually and collectively.

C. THE GLOBAL PHILIPS ENTERPRISE, INCLUDING ALL PHILIPS ENTITIES NAMED AS DEFENDANTS, OPERATES AS A UNIFIED ENTITY KNOWN SIMPLY AS "PHILIPS."

98. Royal Philips controls and oversees all aspects of the Philips businesses around the world, going to great lengths to ensure there is a unity of purpose and vision, consistent execution of company procedures, policies, and goals, and, importantly, maintenance and protection of the valuable "Philips" brand.[36]

99. On its website and in promotional materials, the Philips conglomerate holds itself out to the world as a unified global company that identifies itself simply as "Philips," without distinguishing between or among the various Philips entities.[37] Indeed, Philips proudly proclaims:

[36] For example, in 2019, Royal Philips, Philips NA, and four other Philips entities, filed suit against a company alleging copyright infringement. In their complaint, the Philips entities held themselves out collectively as "Philips" contending that "[t]he six named plaintiffs … are collectively in the business, *inter alia*, of developing, manufacturing, selling, supporting, maintaining, and servicing Philips' medical imaging systems, including the proprietary hardware and software and related trade secrets that are necessary – and/or may be used – to operate, service, and repair such systems." Complaint in *Philips v. 626 Holdings, Inc.*, 9:19-cv-81263-RS (S.D. Fla. 2019), ECF No. 1 (attached hereto as Exhibit "32"), at 5, ¶ 18.

[37] *See generally,* Royal Philips "About us" webpage (Exhibit "1" hereto).

"We are a diverse team made up of some 80,000 individuals across over 100 countries, all with different backgrounds, perspectives and experiences."[38]

100. Royal Philips' effort to unite its various business segments and subsidiaries under one brand and to construct a single Royal Philips image in the public eye is evident in its use of the iconic blue Philips shield:

101. The Philips shield in its present form was debuted in November 2013, as a result of Royal Philips' rebranding campaign and appears on the facade of the company's headquarters in Amsterdam.[39]

102. That very same Royal Philips shield appears at the bottom of every Philips entity's website, including the Respironics site and the Philips websites that are intended for access by foreign consumers in other countries around the world.[40] It also appears on the user manuals and marketing materials of the Recalled Devices.[41]

---

[38] *Id.*

[39] *See* Royal Philips Press Release, Philips unveils new brand direction centered around innovation and people (Nov. 13, 2013), https://www.philips.com.qa/a-w/about/news/archive/standard/news/2013/20131113-Philips-unveils-new-brand-direction-centered-around-innovation-and-people.html (last accessed Oct. 8, 2022) (attached hereto as Exhibit "160").

[40] *See, e.g.*, Philips Respironics website – About Philips Respironics (Exhibit "101" hereto); Philips Egypt website, https://www.philips.com.eg/ (last accessed Oct. 7, 2022) (attached hereto as Exhibit "161"); Philips Australia website, https://www.philips.com.au/?locale_code=en_au (last accessed Oct. 7, 2022) (attached hereto as Exhibit "162"); Philips Chile website, https://www.philips.cl/?locale_code=es_cl (last accessed Oct. 7, 2022) (attached hereto as Exhibit "163").

[41] *See, e.g.*, DreamStation User Manual (Exhibit "47" hereto), at 33; REMstar SE User Manual (Exhibit "48" hereto), at 25; Trilogy 100 User Manual (Exhibit "49" hereto), at 2; Philips

103. Royal Philips similarly uses its Philips "wordmark" to hold out a public image that is seamless among the various Philips entities.

104. Royal Philips has stated that "[t]he Philips wordmark is our primary and most recognized logo," and commercial use of the wordmark is managed by the Royal Philips Brand Team.[42] That same Philips wordmark is featured prominently at the top of the websites of various Philips entities around the world.[43]

105. In order to achieve consistency and a unified global presence, Royal Philips utilizes "a worldwide communication and training program" that includes "mandatory sign-off on the [company's] General Business Principles."[44] Royal Philips established these "General Business Principles" in order to "set the standard for acting with integrity at Philips."[45] According to the company: these fundamentals "govern all our decisions and actions throughout the world and apply equally to our group actions and to our conduct as individuals."[46]

Respironics DreamStation Brochure (Exhibit "44" hereto), at 4; Philips Respironics DreamStation Family Brochure (Exhibit "77" hereto), at 1.

[42] *See* Royal Philips website, Philips Wordmark, https://www.philips.com/a-w/about/news/media-library/20170101-Philips-Wordmark.html (last accessed Oct. 7, 2022) (attached hereto as Exhibit "164").

[43] *See, e.g.*, Philips Egypt website (Exhibit "161" hereto); Philips Australia website (Exhibit "162" hereto); Philips Chile website (Exhibit "163" hereto).

[44] *See* Royal Philips website, General Business Principles, https://www.philips.com/a-w/about/investor-relations/governance/business-principles (last accessed Oct. 3, 2022) (attached hereto as Exhibit "33").

[45] *Id.*

[46] *Id.*

106. Additionally, Royal Philips touts "a single standard operating model that defines how we work together effectively to achieve our company objectives – the Philips Business System (PBS)…. Having a single business system increases speed and agility, and enhances standardization, quality and productivity, while driving a better, more consistent experience for our customers."[47] PBS is "an interdependent, collaborative operating model that covers all aspects of how we operate,"[48] thereby signaling that Royal Philips intends all of its subsidiaries to depend on each other and function as one.

107. The PBS "is leveraged to drive operational excellence and removes irregularity caused by various operating models of recently acquired businesses."[49] PBS includes "Governance" as a key aspect: "[c]lear governance, roles and responsibilities empower people to collaborate and act fast."[50]

108. When Royal Philips first announced the Recall on June 14, 2021, the company stated on its website: "To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam."[51]

109. Shortly after the Recall, Royal Philips' Chief Executive Officer ("CEO") Frans van Houten announced that: "In connection with the voluntary recall notification in June of this year,

---

[47] Royal Philips 2021 Annual Report (Exhibit "13" hereto), at 12.

[48] *Id.* at 117.

[49] *Id.* at 233.

[50] *Id.* at 12.

[51] Royal Philips Press Release, Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices (June 14, 2021), https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "34").

the FDA has recently conducted an inspection of a Philips Respironics manufacturing facility in the US."[52] Mr. van Houten assured Philips' shareholders and the public that: "We will work closely with the FDA to clarify and follow up on the inspectional findings and its recent requests related to comprehensive testing. Until we have concluded these discussions, we are not able to publicly provide further details on these responses. We remain fully committed to supporting the community of patients who rely on the affected devices, and the physicians and customers who are dedicated to meeting patient needs."[53]

110. A year later, as part of its response to the Recall, Royal Philips' CEO van Houten announced that the Philips company is "focused on further unifying and centralizing our business processes and systems to ensure that we are driving a patient centric and quality culture mindset throughout the company at all times."[54]

111. The "Philips" brand is important to the company: "For some 130 years, our meaningful innovations have improved the quality of life for millions of people around the world, creating **a strong and trusted Philips brand**."[55] In fact, Philips advertises that "[w]ith a 2021

[52] Royal Philips Press Release, Philips provides update on earlier announced voluntary CPAP, BiPAP and Mechanical Ventilator recall notification* (Nov. 14, 2021), https://www.philips.com/a-w/about/news/archive/standard/news/articles/2021/20211113-philips-provides-update-on-earlier-announced-voluntary-cpap-bipap-and-mechanical-ventilator-recall-notification.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "35").

[53] *Id.*

[54] *See* Philips video titled "Philips CEO Frans van Houten and Chief Business Leader Connected Care Roy Jakobs talk about the various aspects of the field safety notice*," available at: https://www.philips.com/a-w/about/investor-relations/recall-sleep-and-respiratory/testing.html (last accessed Oct. 3, 2022).

[55] *See* Royal Philips "About us" webpage (Exhibit "1" hereto).

brand value in excess of USD 12 billion, as defined by branding agency Interbrand, **Philips is one of the world's strongest brands**."[56]

112. In support of its contention that the company is a single, global enterprise, Philips boasts: "Over the past decade we have transformed into a focused leader in health technology."[57] "At Philips, our purpose is to improve people's health and well-being through meaningful innovation. We aim to improve 2.5 billion lives per year by 2030, including 400 million in underserved communities."[58]

113. Royal Philips employs a Chief Medical Officer to achieve those goals. The Chief Medical Officer performs the following functions:

- "Overall functional leadership for clinical innovation, clinical strategy, medical affairs and health economics activities of the company";
- "work[ing] closely and collaboratively with business and functional leaders across the organization";
- "driv[ing] the development and implementation of Philips' medical strategies across the Health Continuum, from the perspective of consumers, patients, and providers";

[56] *See* Royal Philips website, https://www.philips.com/a-w/about/our-brand (emphasis added) (last accessed Oct. 3, 2022) (attached hereto as Exhibit "36"). Philips is ranked 57 in the Best Global Brands by Interbrand, *see* https://interbrand.com/best-global-brands/philips/ (*see* the video on this page titled "Global Panel: Business Transformation," where Royal Philips' Lorraine Barber-Miller, EVP and Chief Marketing & E-Commerce Officer, discusses Philips' global branding). In her role, Ms. Barber-Miller "[l]ead[s] 3000+ practitioners globally with an annual budget of $1.3 billion across all…lines of business, and market segments" to "[d]riv[e] enterprise-wide marketing." *See* LinkedIn Profile for Lorraine Barber-Miller, Experience section, https://www.linkedin.com/in/lorrainebarbermiller/ (last accessed Oct. 3, 2022) (attached as Exhibit "37" hereto).

[57] *See* Royal Philips "About us" webpage (Exhibit "1" hereto).

[58] *Id.*

- "development of strategic relations with highly respected academic institutions and other strategic partners";
- "clinical trial programs in support of existing and next generation products";
- "provid[ing] clinical guidance for the development and market introduction of all new products, solutions and services"; and
- "advis[ing] Philips' board and management in making decisions on market participation, product development, clinical development programs, business development and product launches."[59]

114. Philips is proud of its place in history: "We have a proud heritage of ground-breaking innovation that stretches back almost 130 years. Meaningful innovation – focused on our customers' needs – remains at the heart of everything we do."[60] The company points out that "Products come and go ... Technologies change ... But Philips is still about one thing: Creating meaningful innovation that improves people's health and well-being."[61]

115. Included as part of its long history of innovation, is Philips' intellectual property rights.[62] Philips tightly controls and protects all of its intellectual property, including that of its CPAP, BiPAP, and ventilator devices, in various ways.

[59] *See* LinkedIn Profile for Royal Philips Chief Medical Officer Jan Kimpen, Experience section, https://www.linkedin.com/in/jankimpen/ (last accessed Oct. 3, 2022) (attached as Exhibit "38" hereto).

[60] *See* Royal Philips "About us" webpage (Exhibit "1" hereto).

[61] *Id.* at 3 (Royal Philips copyrighted webpage representing Royal Philips invested €1.8 billion in R&D in 2021 and holds 57,000 patent rights for its health technology business under the "supervision" of Royal Philips' Executive Committee and Supervisory Board).

[62] *Id.*

116. First, Royal Philips touts its Intellectual Property & Standards (IP&S) segment as an "Integrated Intellectual Asset Management" in order to **"manage all forms of IP for each of Philips' business areas."**[63] "Philips' IP&S proactively pursues the creation of new Intellectual Property (IP) and the protection of existing IP in close co-operation with Philips' operating businesses and Innovation & Strategy."[64]

> IP&S is a leading industrial IP organization providing world-class IP solutions to Philips' businesses to support their growth, competitiveness and profitability. Royal Philips' IP portfolio currently consists of 57,000 patent rights, 33,000 trademarks, 114,000 design rights and 2,900 domain names. Philips filed 860 new patents in 2021, with a strong focus on the growth areas in health technology services and solutions. Philips earns substantial annual income from license fees and royalties.[65]

117. Second, Royal Philips used a company named RIC Investments, LLC ("RIC") for its patenting. RIC was, initially, a wholly-owned subsidiary of Respironics, Inc., and an assignee of various patents.[66] Thereafter, RIC became a wholly-owned subsidiary of Royal Philips including, for the last time, in a Royal Philips' 2017 Form 20-F filing.[67] As of 2018, RIC no longer appears on the Form 20-F, but an entity named Philips IP Ventures B.V. is listed as a Royal Philips' subsidiary.[68]

---

[63] *See* Philips IP&S corporate video (Sept. 8, 2016), available at: https://www.youtube.com/watch?v=oXGlmpNSCHQ (last accessed Oct. 3, 2022), at 1:25-1:40.

[64] *See* Philips 2021 Annual Report (Exhibit "13" hereto), at 84.

[65] *Id.* at 22.

[66] *Respironics, Inc. v. Invacare Corp*., 437 F. App'x 917, 918 (Fed. Cir. 2011).

[67] *See* Royal Philips 2017 SEC 20-F filing, Exhibit 8, List of subsidiaries (Exhibit "20" hereto).

[68] *See* Royal Philips 2018 SEC Form 20-F filing, Exhibit 8, List of subsidiaries, available at: https://www.results.philips.com/publications/ar18 (last accessed Oct. 7, 2022) (attached hereto as Exhibit "144").

a. Early patents believed to be related to Philips' CPAP machines were assigned to RIC.[69] Similarly, early Canadian patents involving CPAP and BiPAP devices were filed by Respironics or RIC Investments and then assigned to Philips RS.[70]

b. U.S. patents believed to be related to Philips' CPAP or BiPAP devices that were filed by RIC or by Respironics, Inc. were assigned to Royal Philips.[71]

c. U.S. patents believed to be related to Philips' CPAP or BiPAP devices were filed by Royal Philips and assigned to RIC (inverse of above).[72] These patents reveal the comingling of inventors from Pennsylvania and the Netherlands.[73]

d. U.S. patents filed by and assigned to Royal Philips have inventors listed as employees of Philips RS.[74]

118. Third, Royal Philips and Philips RS jointly prosecute Philips' CPAP patent infringement and unfair competition cases. For example, both Royal Philips and Philips RS were complainants in two related cases, one filed with the U.S. International Trade Commission

[69] *See, e.g.*, Estes, *et al.*, *Method and Apparatus for Providing Positive Airway Pressure to a Patient*, Patent No. US 6,932,084 B2, Aug. 23, 2005 (attached hereto as Exhibit "145"), at 1.

[70] *See, e.g.*, Canadian patents: CA 2463488 filed by RIC Investments, at 1; CA 2410248 filed by Respironics, at 1; and CA 2497915 filed by RIC, at 1. Each of these lists Philips RS North America LLC as owner (attached hereto as Exhibits "146," "147," and "148," respectively).

[71] *See, e.g.*, Jaffe, *et al.*, *Nasal and Oral Patient Interfaces*, Patent No. US 10,105,099 B2 (Oct. 23, 2018) (attached hereto as Exhibit "149"), at 1.

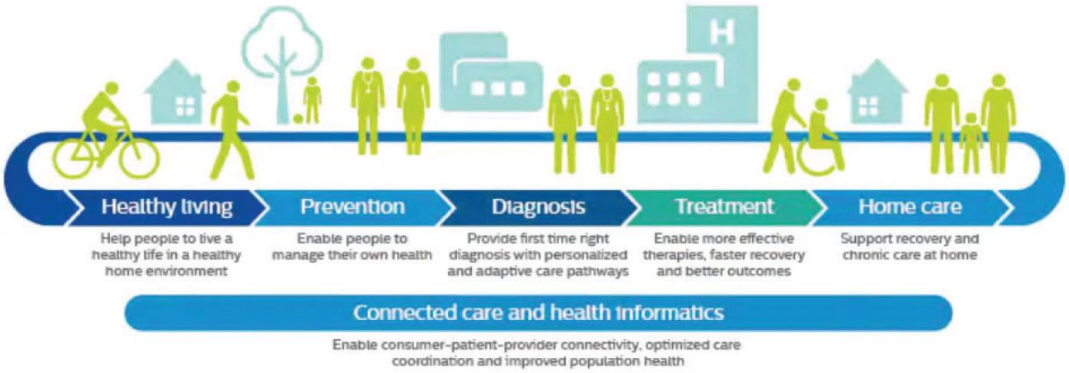
[72] *See, e.g.*, Ho, *et al.*, *Textured/Polished Respiratory Mask Seal and Mask*, Patent No. US 9,399,107 B2 (July 26, 2016) (attached hereto as Exhibit "150"), at 1.

[73] *See, e.g., id.*

[74] *See, e.g.*, Shelly, *et al.*, *Automatic Pressure Titration*, Patent No. US 9,7344,322 B2 (Aug. 29, 2017) (attached hereto as Exhibit "151"), at 1 (listing Heather Ressler as an inventor); *see also* Matthews, *et al.*, *Starting Pressure for Respiratory Therapy Devices*, Patent No. US 10,286,165 B2 (May 14, 2019) (attached hereto as Exhibit "152") (listing Gregory Matthews as an inventor); LinkedIn profile for Greg Matthews, https://www.linkedin.com/in/greg-matthews-96a0491/ (attached hereto as Exhibit "153"); LinkedIn profile for Heather Ressler, https://www.linkedin.com/in/heather-ressler-5298716/ (attached hereto as Exhibit "154").

("USITC") and another in the District of Delaware, alleging unfair trade practices based upon infringing certain Philips' CPAP patents.[75] The *same* counsel represents both Royal Philips and Philips RS in these actions. Further, the USITC complaint refers to Royal Philips and Philips RS collectively as "Philips" and reflects that Royal Philips and Philips RS act as an integrated unit generally and, specifically, with respect to Philips' Sleep and Respiratory Care business, averring as follows:

> 9. Since its founding in 1891, Philips has dedicated significant resources to research and development for the advancement of technology used around the world through its business units including those described below. Philips strives to make the world heathier and more sustainable through innovation with the goal of improving the lives of billions of people. Philips approaches healthcare as a continuum where its technologies can be applied across activities of healthy living, prevention, diagnosis, treatment and home care as depicted in this graphic:



***

> 12. Philips as a company is organized through various subsidiaries into four segments. These are: (1) Philips Diagnosis and Treatment; (2) Philips Connected Care and Health Informatics; (3) Philips Personal Health; and (4) an "other" segment that includes central administration and certain miscellaneous operations. *See* https://www.philips.com/a-w/about/news/archive/standard/news/press/2019/20190110-philips-realigns-the-

[75] *See In the Matter of Certain UMTS and LTE Cellular Communication and Products Containing the Same*, Inv. No. 337-TA-1240 (USITC Dec. 17, 2020) ("USITC case") (attached hereto as Exhibit "155") and *Koninklijke Philips, N.V. v. Thales DIS AIS USA LLC et. al*., No. 1:20-cv-01713-CFC (D. Del. Dec. 17, 2020) (attached hereto as Exhibit "156").

composition-of-its-reporting-segments.html.[76] These four segments are further broken down into several separate entrepreneurial business units. The domestic business unit that is relevant to this investigation is Philips' Sleep ("Philips Sleep"), which is part of Philips RS North America LLC (f/k/a Respironics, Inc.), a wholly owned subsidiary of KPNV. Philips Sleep has made significant domestic investments in plant and equipment, and research and development directed to products practicing one or more claims of each of the Asserted Patents.

13. Philips Sleep falls within the Sleep and Respiratory Care business of the Philips Connected Care Segment. *See* https://www.usa.philips.com/c-e/smartsleep.html.[77] **Philips Sleep developed the hardware and software behind the Continuous Positive Airway Pressure ("CPAP") Devices described herein, including products that have been or are being developed and sold by Philips Sleep in the United States supporting United States domestic industry.**

14. **Through this Philips Sleep business unit, Philips researches and develops sleep therapy devices with monitoring technology, develops and sells products that allow individuals to monitor and improve their health, and transfers or licenses its technologies and/or the patents that protect its technologies to customers who use the technologies in their products. As a result of these efforts, Philips has become a world leader in health monitoring technology and innovation, including sleep therapy devices such as its CPAP devices, and a major contributor to the United States economy and jobs.**

15. **For example, Philips Sleep produces products that have been or are being developed and sold in the United States, including sleep therapy devices such as CPAP devices, which are used by patients with sleep apnea and which collect various information that can be transmitted, for example, to clinicians and the user's own devices to monitor the patient's progress and manage patient compliance and therapy. The connected care system utilizing the CPAP devices (e.g., DreamStation, DreamStation2, SystemOne, DreamStation Go (DsGo), etc.) integrates UMTS and LTE Cellular Communication Modules to communicate through the cellular network to clinical products such as Care Orchestrator (predecessor EncoreAnywhere) and patient products such as DreamMapper.**
https://philipsproductcontent.blob.core.windows.net/assets/20200424/adf8ec9a993041e8a097aba700e2c68e.pdf.[78] Philips enables the care of more than 9.7 million people through cloud-based patient monitoring systems.

[76] Last accessed Oct. 7, 2022.

[77] Last accessed Oct. 7, 2022.

[78] Unable to access link as of Oct. 7, 2022.

> 16. The Philips Sleep business unit expands Philips' capabilities in personal health management and supports Philips' longstanding commitment to deliver integrated solutions across the health continuum.
>
> 17. A domestic industry exists … relating to Philips Sleep's DreamStation, DreamStation2, SystemOne, DreamStation Go (DsGo) protected by the Asserted Patents, including related products, based on **Philips Sleep's large investments made in plant and equipment, employment of labor and capital, domestic manufacturing, assembly, testing, engineering, and research and development, among other activities.**
>
> 18. A domestic industry is also in the process of being established … relating to Philips Sleep's DreamStation2 and DreamStation Go products protected by the Asserted Patents. **Philips Sleep has taken concrete steps in the form of significant investments in plant and equipment, labor and capital, testing, engineering and research and development to establish a domestic industry in the DreamStation2 and DreamStation Go products**, which are expected to be commercially released during 2021, and therefore there is a significant likelihood that this industry will be established in the near future.[79]

119. Again, much of the information regarding the specific activities involving Philips' intellectual property, including Royal Philips and the individual Philips' units and their employees, is shielded from public view. Formal discovery into Philips' patent research, development, and rights would shed light on Royal Philips' control over and ownership of the intellectual property related to the Recalled Devices. However, from records that are available publicly, Royal Philips was involved with, controlled, prosecuted, and defended the intellectual property of the Recalled Devices.

120. Philips claims its "management structure combines responsible leadership and independent supervision."[80] The company explains that "[t]he Executive Committee operates under the chairmanship of the Chief Executive Officer and supports the Board of Management in

[79] *See* USITC case (emphasis added).

[80] *Id.*

the deployment of Philips' strategy and policies, and the achievement of its objectives and results."[81]

121. Royal Philips' Executive Committee – its managing body – is in charge of developing the "Risk Appetite" for the whole of the Philips Group.[82] The Executive Committee "identifies and manages the risks Philips face in realizing its objectives,"[83] referring to Royal Philips and its subsidiaries. In performing its risk management, the Executive Committee considers information from both internal and external sources, including from its subsidiaries.

122. Since at least 2017, each of the named operating segments of the Philips enterprise has had representation in the form of a "Business Leader" on Royal Philips' Executive Committee.[84] For example, Mr. Roy Jakobs, who is in charge of Philips' Connected Care

[81] *See* Royal Philips website, https://www.philips.com/a-w/about/executive-committee.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "39"). "Under the chairmanship of the President/Chief Executive Officer (CEO), and supported by the other members of the Executive Committee, the members of the Board of Management drive the company's management agenda and share responsibility for the continuity of the Philips group, focusing on long-term value creation." Philips 2021 Annual Report (Exhibit "13" hereto), at 117.

[82] *See* Royal Philips 2021 Annual Report (Exhibit "13" hereto), at 79.

[83] *Id.*

[84] *See* Royal Philips 2017 SEC Filing (Exhibit "20" hereto), at 49, 53, 58.

businesses that include Philips RS[85] (and who is scheduled to become the CEO for Royal Philips on October 15, 2022[86]), sits on the Executive Committee.[87]

123. In its 2021 Annual Report, Royal Philips discusses the creation of Innovation Hubs "[t]o drive innovation, effectiveness and efficiency, and to enable locally relevant solution creation."[88] The locations of these hubs are in Eindhoven (Netherlands), Cambridge (USA), Bangalore (India), and Shanghai (China).[89] Importantly "[t]he four hubs form a global network, together with the other smaller innovation and research sites in their respective regions, to provide access to each other's capabilities to serve businesses, markets and customers globally."[90]

124. According to Royal Philips, the Eindhoven Hub is "Philips' largest cross-functional Innovation Hub, hosting the global headquarters of most of our central innovation organizations. Many of the company's core research programs are also run from here, as well as innovation for solution & services delivery."[91]

---

[85] *See* Royal Philips First-Quarter Results 2022 (Apr. 25, 2022), available at: https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-first-quarter-results-2022.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "40") ("Philips has a strong program management in place led by Roy Jakobs, Chief Business Leader of the Connected Care businesses and member of Philips' Executive Committee, to ensure the Respironics field action is executed with speed and accuracy.").

[86] *See* Royal Philips Press Release, Philips announces CEO succession (Aug. 16, 2022), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2022/20220816-philips-announces-ceo-succession.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "41").

[87] *See* Royal Philips Chief Business Leader of Connected Care, Roy Jakobs, Profile, https://www.philips.com/a-w/about/executive-committee/roy-jakobs.html (last accessed Oct. 9, 2022) (attached hereto as Exhibit "42").

[88] Royal Philips 2021 Annual Report (Exhibit "13" hereto), at 21.

[89] *Id.* at 22.

[90] *Id.*

[91] *Id.*

125. The Cambridge Hub is "located at the heart of medical innovation within the North America market. It has innovation partnerships with top engineering institutions like MIT, with top clinical sites, and with government funding agencies like NIH (National Institutes of Health) and BARDA (Biomedical Advanced Research and Development Authority)."[92]

126. Philips' drive for company-wide standardization extends to other aspects of the Philips enterprise. For example, "Philips runs an Integrated Supply Chain, which encompasses supplier selection and management through procurement, manufacturing across all the industrial sites, logistics and warehousing operations, as well as demand/supply orchestration."[93]

127. Further, Philips invests in "embedding quality in our organizational culture as well as consolidating and standardizing our Quality Management Systems (QMS). … With consistency of purpose, **top-down accountability**, consolidation, standardization and continuous improvement, we aim to drive the adoption of a quality mindset as well as improved quality and safety outcomes throughout the enterprise. . .Quality is an integral part of the evaluation of all levels of management. We perform extensive programs to monitor and evaluate product performance and correct or remove any product from service that presents harm to patients or users. In the event of issues we run extensive programs with the goal of recalling, repairing or replacing affected products and attempting to prevent such issues from reoccurring."[94]

128. Despite conducting and presenting itself as a cohesive, unified company, with uniform business standards and operating procedures designed to maintain and protect the Philips brand, in dealings with customers, suppliers, patients, doctors, and regulatory bodies, Royal Philips

[92] *Id.*

[93] *Id.* at 25.

[94] *Id.* at 85 (emphasis added).

has created a complex, confusing, and ever-changing labyrinth of interrelated and interconnected Philips entities and holding companies throughout the world.[95] Much of the information regarding the specific activities of the individual Philips units and their employees is shielded from public view. Formal discovery into Philips' corporate structure would shed light on the level of Royal Philips' control over and ownership of the specific entities involved in the allegations related to the responsibility for the Recalled Devices. However, from records that are available publicly, Royal Philips was involved with and controlled not only the sales and marketing of the Recalled Devices, but also the decisions regarding PE-PUR foam, and the recall of the devices containing PE-PUR foam.

III. JURISDICTION AND VENUE

129. The Court has subject matter jurisdiction under 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5 million, exclusive of interest and costs, and is a class action in which Plaintiffs and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. § 1332(d)(2)(A).

130. Each Philips Defendant has significant contacts with the Western District of Pennsylvania such that they are subject to personal jurisdiction of the Court. Further, when convenient for Royal Philips, the company concedes it is subject to personal jurisdiction of the Court. For example, in the *SoClean, Inc. v. Koninklijke Philips N.V., et al.*, 2:22-cv-542 litigation, transferred to *In re SoClean, Inc. Marketing, Sales Practices and Prod. Liab. Litig.*, MDL No. 3021 (W.D. Pa.), counsel for Royal Philips filed a Declaration stating that "KPNV [Royal Philips]

[95] Royal Philips 2020 SEC filing, Exhibit 8, List of Subsidiaries (Exhibit "16" hereto).

acknowledged and conceded that it was subject to specific personal jurisdiction in Pennsylvania on the claims asserted by SoClean in th[at] action."[96]

131. This Court has personal jurisdiction over each Philips Defendant for the additional reason that they have engaged in substantial, systematic and continuous contacts with Pennsylvania by, *inter alia*, regularly conducting and soliciting business in Pennsylvania and this District, deriving substantial revenue from products and/or services provided to persons in Pennsylvania and this District.

132. When this litigation first commenced, the same lawyers represented both Philips NA and Philips RS. Both entities argued in front of the Judicial Panel on Multidistrict Litigation for consolidation in Massachusetts, where Philips NA is headquartered. According to their joint brief, "the District of Massachusetts has the strongest nexus to the litigation." MDL No. 3014, Dkt. No. 47 at 13 (J.P.M.L. July 29, 2021). However, they also argued that alternatively, "a clear nexus to the matter …, the Western District of Pennsylvania is home to the other defendant, Philips RS North America LLC (with headquarters in Murrysville, PA) and is also well-equipped to handle the consolidated actions." *Id*. at 8.

133. Venue is proper in this District on account of the MDL designation pursuant to 28 U.S.C. § 1407 and under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this District.

[96] *See* Declaration of William B. Monahan in Support of Motion to Dismiss, Case 2:22-mc-0152-JFC, at ECF 126-1 (attached hereto as Exhibit "43").

IV. FACTUAL ALLEGATIONS

A. CPAP AND BIPAP MACHINES AND VENTILATORS ARE PRESCRIBED TO TREAT BREATHING DISORDERS.

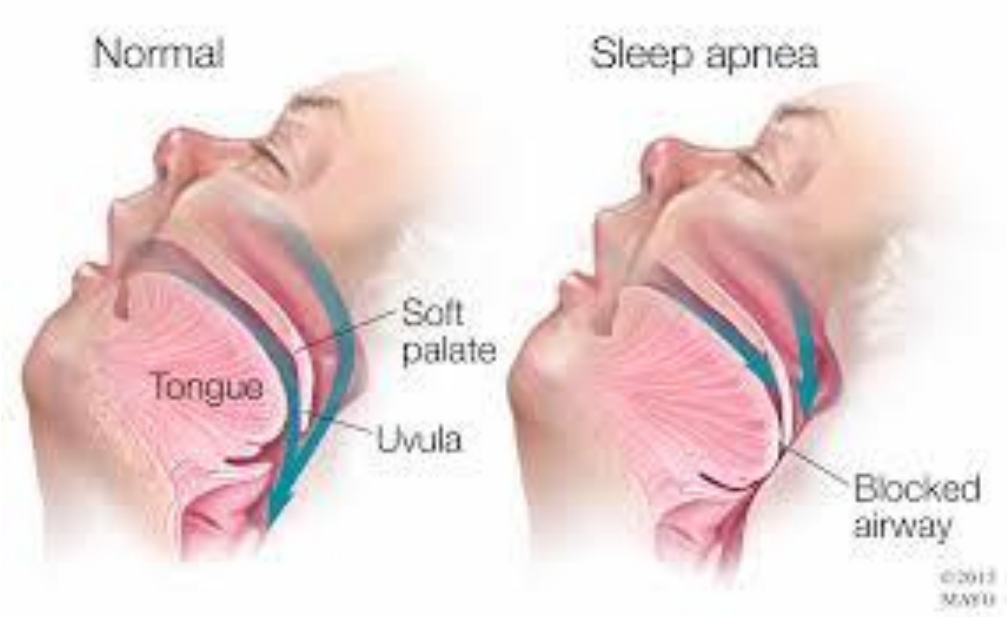
134. Sleep apnea is a sleeping disorder in which breathing is disturbed during sleep. These disturbances are called "apneas."

135. According to the Mayo Clinic, the main types of sleep apnea are obstructive sleep apnea, central sleep apnea, and complex sleep apnea syndrome (also known as treatment-emergent central sleep apnea).

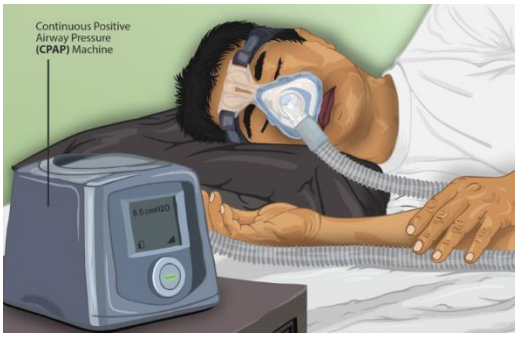
136. Obstructive sleep apnea is the most common type of sleep apnea. It occurs when the muscles in the back of the throat relax during inhalation, which causes the airway to narrow or close and prevent sufficient air from passing through. This in turn lowers the oxygen level in the blood, which causes the brain briefly to wake the body from sleep to reopen the airway. This reawakening may be so brief that the patient does not remember it, and it may be associated with snorting, choking, or gasping. It can happen anywhere from a few times per hour to once every few minutes, and can prevent the patient from reaching the deep, restful phases of sleep.

137. Central sleep apnea occurs when the brain fails to transmit signals to the breathing muscles. As a result, the body stops breathing, which can cause waking with shortness of breath, difficulty getting to sleep, or difficulty staying asleep.

138. Complex sleep apnea syndrome occurs when a patient has both obstructive sleep apnea and central sleep apnea. An image showing how an airway can be blocked as a result of sleep apnea appears below:



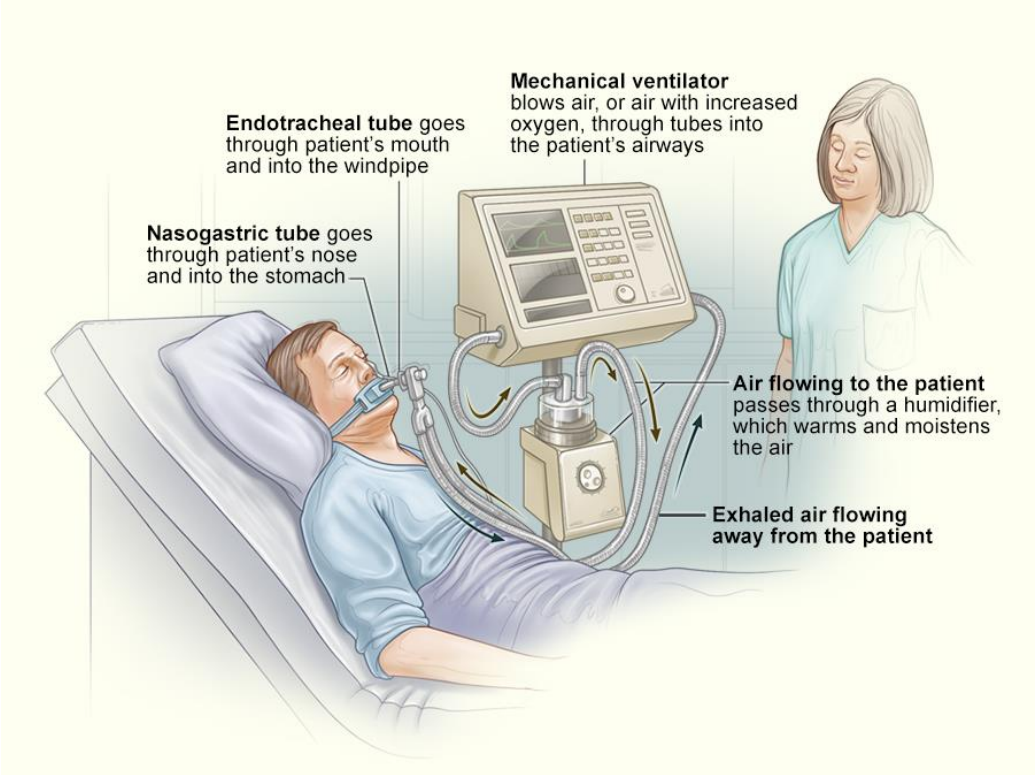
139. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a continuous flow of air through a mask that is placed over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea. The illustration below shows a generic CPAP machine being used by a patient while sleeping.



140. Another therapy to treat sleep apnea includes use of BiPAP machines, which use two different pressures – one for inhaling and one for exhaling.

141. Patients customarily place CPAP or BiPAP machines on a nearby nightstand or shelf. A hose connects the unit to a mask, which is worn over the nose or mouth during sleep. Below is an image of a Philips DreamStation machine on a nightstand.

142. Ventilators are often used to treat respiratory failure. Ventilators push air into and out of the patient's lungs like a bellows, typically through a tube that is connected to the machine on one end and inserted through the patient's nose or mouth into the trachea on the other end. Patients are typically sedated while on ventilation because it can otherwise cause intense pain. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. There are also ventilators for home use. The following image from the National Institute of Health ("NIH") shows a typical ventilator and how it works:



B. THE EVOLUTION OF CPAP, BIPAP, AND VENTILATOR DEVICES CONTAINING PE-PUR FOAM.

143. The basic technology used in CPAP and BiPAP devices was developed in 1980 by an Australian pulmonologist, Dr. Colin Sullivan, who used it to treat dogs with respiratory problems, before the technology was adapted for humans.

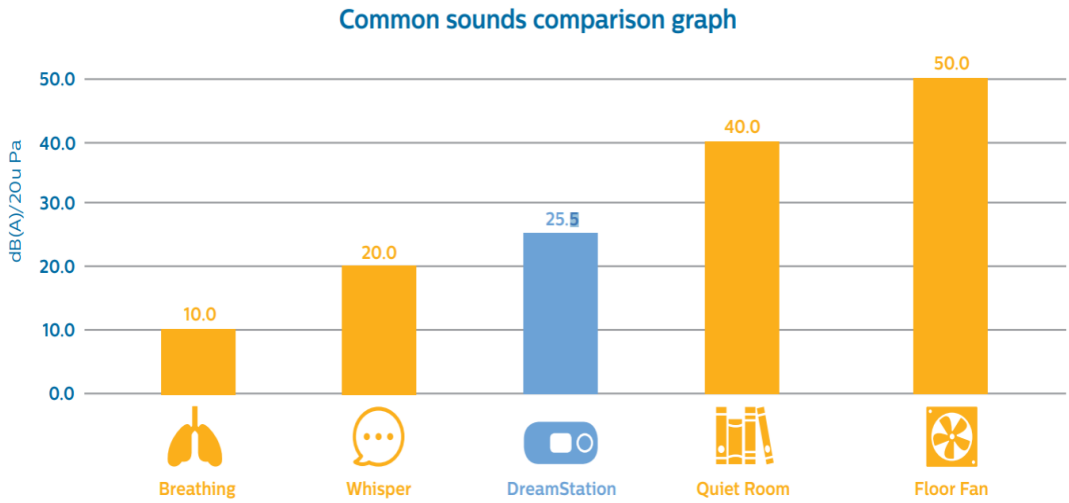
144. Respironics commercialized this technology and sold the first publicly available CPAP device in 1985. ResMed, an industry competitor, followed with the release of its CPAP device in 1989.

145. These first-generation CPAP and BiPAP devices created a new and commercially viable field of respiratory therapy. The devices, however, were large and noisy, resulting in an "arms-race" between manufacturers to develop devices that were smaller, more responsive to patient breathing patterns, and quieter.

146. The noise level of CPAP and BiPAP devices became a driver of adult consumer preference because loud devices interrupted the peaceful sleep of both the patient and their partner.

147. To develop the quietest devices on the market with the lowest decibel ratings, some device manufacturers including Philips filled the CPAP, BiPAP, and ventilator devices with sound abating foam to reduce the volume of noise emitted from the devices.

148. In fact, the alleged relative quiet nature of the DreamStation products with PE-PUR foam factored prominently into Philips' marketing.[97] Philips represents that it extensively studied and measured the amount of sound produced by DreamStation products. Philips even included an infographic indicating DreamStation products are barely louder than a whisper:[98]



149. Other manufacturers did not utilize foam for sound abatement, instead they utilized silencing technology to abate the sound from the devices.

[97] *See* Philips Respironics DreamStation Brochure, available at: https://www.documents.philips.com/assets/20170523/62e4f43a1349489ba3cca77c0169c6ef.pdf (last accessed Oct. 3, 2022) (attached hereto as Exhibit "44").

[98] *See id.* at 3.

150. Philips manufactures and sells CPAP and BiPAP machines and ventilators, among other products. According to Royal Philips' 2020 Annual Report,[99] Sleep & Respiratory Care ("SRC") constituted 49% of its total sales in its Connected Care line of business,[100] which, in turn, accounted for 28% of Royal Philips' overall sales of about €19.5 billion. Philips has sold millions of CPAP, BiPAP, and ventilator devices in the United States and elsewhere throughout the globe. In 2021, there was "a 23% decline in [Royal Philips'] Connected Care businesses. This was largely due to the Respironics recall…"[101]

151. Philips provides a User Manual with its CPAP, BiPAP, and ventilator devices. Royal Philips owns the copyright to all, or most, of those User Manuals.[102]

152. Philips made the decision to use PE-PUR foam for sound abatement purposes in its CPAP, BiPAP, and ventilator devices. That decision was made for products distributed by Philips' entities throughout the globe including, but not limited to the United States, Australia, Canada, Israel, and Chile.[103]

---

[99] *See* Royal Philips 2020 Annual Report, available at: https://www.results.philips.com/publications/ar20 (last accessed Oct. 7, 2022) (attached hereto as Exhibit "45").

[100] *Id.* at 18. Prior to 2019, SRC was part of Philips' Personal Health businesses. *See* Royal Philips 2018 Annual Report, available at: https://www.philips.com/c-dam/corporate/about-philips/sustainability/downloads/other/philips-full-annual-report-2018.pdf (last accessed Oct 4, 2022) (attached hereto as Exhibit "46"), at 5.

[101] Royal Philips 2021 Annual Report (Exhibit "13" hereto), at 28.

[102] *See, e.g.*, DreamStation User Manual (attached hereto as Exhibit "47"), at 2; REMstar SE User Manual (attached hereto as Exhibit "48"), at 2.

[103] *See* Royal Philips Q2 2022 Results, available for download at Philips Q2 2022 Quarterly Results | Philips Results (last accessed Oct. 3, 2022) (attached hereto as Exhibit "50"), at 33.

153. Polyurethane is an organic polymer in which urethane groups connect the molecular units. It is usually formed by reacting a diisocyanate or triisocyanate with a polyol. Under certain circumstances, polyurethane may break down into a diisocyanate or triisocyanate.

154. The two main types of polyurethane are polyester and polyether. Polyester polyurethane has better shock absorption and vibration dampening properties and is commonly used for soundproofing or sound dampening.

155. It has been known for decades that polyester polyurethane is susceptible to hydrolysis, the chemical breakdown of a compound due to reaction with water, particularly in medical applications. For example, a chapter of a scientific encyclopedia published in 2013 states: "Poly(ester urethanes) were the first generation of PURs used in medical devices but were found unsuitable for long-term implants because of rapid hydrolysis of the polyester soft segment."[104]

156. Polyether polyurethane, on the other hand, is less prone to hydrolysis. The same scientific encyclopedia chapter notes that polyether polyurethanes "with excellent hydrolytic stability replaced poly(ester urethanes) and have been used in medical devices for the past two decades."[105]

157. There were readily available alternative designs available to Philips, other than to use PE-PUR foam in CPAP, BiPAP, and ventilator devices for sound abatement. These include, for example, other types of sound abating foam and silencing technologies that do not use foam.

---

[104] Pal Singh Chauhan, N., and Kumari Jangid, N., "Polyurethanes and Silicone Polyurethane Copolymers," Chapter in Encyclopedia of Biomedical Polymers and Polymeric Biomaterials, January 2013, available at: https://www.researchgate.net/publication/236144965_POLYURETHANES_AND_SILICONE_POLYURETHANE_COPOLYMERS (last accessed Oct. 3, 2022).

[105] *Id.*

158. For example, Philips' principal competitor, ResMed, uses polyether polyurethane foam or silicone-based foam, not PE-PUR foam, for sound dampening.[106]

C. PHILIPS DESIGNED, MANUFACTURED, AND MARKETED ADULTERATED CPAP, BIPAP, AND VENTILATOR DEVICES.

1. Royal Philips Was Directly Involved With Launching And Marketing The Recalled Devices.

159. Philips designed and manufactured CPAP and BiPAP devices and ventilators, including the Recalled Devices.

160. From as early as 2009, Royal Philips took a lead role in launching and marketing several of the Recalled Devices. It did so by "back[ing] … launches with the requisite support in advertising and promotion"[107]; issuing press releases that promoted the devices; participating in medical device conferences that took place in the United States and elsewhere; and maintaining a sleepapnea.com website that educated consumers and providers on Philips devices. Royal Philips' public statements are replete with examples of this conduct.

161. On June 2, 2009, Philips Respironics issued a press release stating, "Royal Philips Electronics (NYSE:PHG, AEX: PHI) today introduced the Trilogy100 portable at-home life-support ventilator."[108] The Trilogy 100 is one of the Recalled Devices. That same June 2, 2009

---

[106] *See* ResMed website – An update from ResMed's CEO, https://www.resmed.com/en-us/other-manufacturer-recall-2021/ (last accessed Oct. 3, 2022) (attached hereto as Exhibit "51").

[107] Thomson Reuters StreetEvents, Edited Transcript, PHIA.AS – Q1 2017 Koninklike Philips NV Earnings Call (Apr. 24, 2017), https://www.results.philips.com/publications/q117/downloads/files/en/philips-first-quarter-results-2017-transcript.pdf?v=20170723194740 (last accessed Oct. 3, 2022) (attached hereto as Exhibit "52"), at 5.

[108] *See* Philips Respironics Press Release, Philips Respironics, Philips Expands Home Healthcare Commitment with Portable Life-Support Ventilator; Offers Ease of Use, Portability and Versatility for Patient (June 2, 2009), https://web.archive.org/web/20090827084718/http://www.prnewswire.com/mnr/respironics/38626/ (last accessed Oct. 3, 2022) (attached hereto as Exhibit "53").

press release directed media inquiries to Steve Kelly,[109] who at the time, was serving as the Director of Global Public Relations and Corporate Communications of Philips Healthcare.[110] While in this position, he "[m]anaged all public relations and corporate communications initiatives on behalf of the largest sector of Philips Electronics while coordinating activities with the HQ team in Amsterdam."[111]

162. On October 13, 2009, Philips Respironics issued a press release stating, "Royal Philips Electronics (NYSE: PHG, AEX: PHI) today introduced the next generation Philips Respironics Sleep Therapy System at Medtrade 2009, the leading conference and expo for the home medical equipment industry."[112] The Sleep Therapy System referred to in press release was the System One 60,[113] one of the Recalled Devices.

163. On August 29, 2016, Royal Philips issued a press release that, among other things, stated that Royal Philips "will showcase its latest COPD and respiratory solutions at the upcoming European Respiratory Society International Congress (ERS) in London, from September 3-7."[114]

---

[109] *Id.*

[110] *See* LinkedIn Profile for Steve Kelly (Sept. 22, 2022), https://www.linkedin.com/in/stvkly (last accessed Oct. 3, 2022) (attached hereto as Exhibit "54").

[111] *Id.*

[112] Philips Respironics Press Release, Philips Unveils Intelligent Sleep Apnea Therapy System To Home Healthcare Industry (Oct. 13, 2009), http://multivu.prnewswire.com/mnr/brunner/40190/ (last accessed Oct. 3, 2022) (attached hereto as Exhibit "55").

[113] *See id*. (offering media images of the System One 60 device and referring to the "breakthrough System One Humidity Control" and "comfort enhance[ing] System One Resistance Control" features).

[114] *See* Royal Philips Press Release, Philips Raises Awareness for Chronic Obstructive Pulmonary Disease (COPD) with Platinum Sponsorship of Leonard Nimoy Tribute Documentary (Aug. 29, 2016), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2016/20160829-COPD-awareness-with-platinum-sponsorship-Leonard-Nimoy-tribute-documentary.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "56").

164. On September 1, 2016, Royal Philips issued a press release regarding its promotion of the DreamStation CPAP, one of the Recalled Devices, at an international trade show:

> At this year's Internationale Funkausstellung (IFA) in Berlin, Germany, Royal Philips (NYSE: PHG, AEX: PHIA) today announced a range of new products . . . Key product innovations being showcased at IFA 2016 that support Philips' commitment to helping consumers stay healthy, live well and enjoy life include: . . . The Dream Family, comprised of the DreamWear mask, DreamStation CPAP (Continuous Positive Airway Pressure) device, and DreamMapper patient engagement app. . . .[115]

165. The September 1, 2016 press release directed media and others interested in obtaining further information to Netherlands-based Elena Calamo Specchia,[116] who at the time, was working in Royal Philips' Amsterdam office as the Royal Philips Spokesperson and Director of the Royal Philips Group Press Office.[117]

166. Also on September 1, 2016, Royal Philips held a press conference at the IFA trade show,[118] during which Netherlands-based Pieter Nota (who at the time was Royal Philips' CEO of Personal Health Businesses, Chief Marketing Officer, and Member of the Executive Committee and Board of Management)[119] made a presentation promoting the DreamStation as well as other

---

[115] *See* Royal Philips Press Release, Philips Introduces a Wide Range of Connected Personal Health Innovations at IFA 2016 (Sept. 1, 2016), https://www.philips.com/a-w/about/news/archive/standard/news/press/2016/20160901-philips-introduces-a-wide-range-of-connected-personal-health-innovations-at-ifa-2016.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "57").

[116] *Id.*

[117] *See* LinkedIn Profile for Elena Calamo Specchia (Sept. 29, 2022), https://nl.linkedin.com/in/elena-calamo-specchia-b3a17418 (last accessed Oct. 3, 2022) (attached hereto as Exhibit "58").

[118] Royal Philips Press Release, Philips Introduces a Wide Range of Connected Personal Health Innovations at IFA 2016 (Sept. 1, 2016) (Exhibit "57" hereto).

[119] *See* LinkedIn Profile for Pieter Nota, https://de.linkedin.com/in/pieter-nota-5526a235 (last accessed Oct. 3, 2022) (attached hereto as Exhibit "59").

Philips products that were being showcased at IFA.[120] The press conference was live-streamed on Royal Philips' website, www.ifa.philips.com.[121]

167. On January 5, 2017, Royal Philips issued a press release announcing that "Royal Philips" was showcasing its products, including the DreamStation Go, at the International Consumer Electronics Show (CES) in Las Vegas.[122] The press release quoted Pieter Nota as stating, "In areas such as oral health, mother and child care, sleep and respiratory care, heart health, and home monitoring, Philips is showcasing its ecosystem of connected products and services at CES, once again demonstrating its leadership in the world of digital health."[123] As with the September 1, 2016 press release, Royal Philips' Elena Calamo Specchia was again listed as the media contact.[124]

168. On January 24, 2017 in a Royal Philips investor call, CEO Frans van Houten remarked on the "success" of Philips' Dream Family of products and was enthusiastic about introduction of the DreamStation Go, one of the Devices at issue here:

> Building on the success of the Philips' integrated Dream Family solution in the United States, Europe and Japan, we recently introduced a Philips DreamStation

[120] *See* TechEvents YouTube video, Philips Press Conference Full at IFA 2016 (Sept. 1, 2016), available at: https://www.youtube.com/watch?v=ZU5PFn91_oU (last accessed Oct. 3, 2022), at 8:28-10:00.

[121] Royal Philips Press Release, Philips Introduces a Wide Range of Connected Personal Health Innovations at IFA 2016 (Exhibit "57" hereto).

[122] Royal Philips Press Release, Philips Highlights Cloud-Based Innovations at the Forefront of Digital Health During CES (Jan. 5, 2017), https://www.philips.com/a-w/about/news/archive/standard/news/press/2017/20170105-philips-highlights-cloud-based-innovations-at-the-forefront-of-digital-health-during-ces.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "60").

[123] *Id.*

[124] *Id.*

> Go portable CPAP solution. DreamStation Go is a compact and lightweight device designed to provide sleep therapy for travelers with obstructive sleep apnea.[125]

169. On March 7, 2017, Royal Philips issued a press release in which "Royal Philips . . . announced the expansion of its Dream Family of products with the new DreamStation Advanced Therapies" products, which consisted of "the DreamStation Advanced Therapies BiPAP autoSV andAVAPS devices,"[126] both of which are Recalled Devices at issue in this litigation.

170. On April 11, 2017, Royal Philips issued a press release in which "Royal Philips . . . announced the launch of DreamStation Go."[127] Royal Philips' Elena Calamo Specchia was again listed as one of the media contacts on the press release.[128]

171. On April 24, 2017, in a Royal Philips investor call, Royal Philips CFO, EVP and Member of the Board of Management Abhijit Bhattacharya[129] informed investors that Royal Philips would launch the DreamStation Go and provide financial support for the advertising and promotion of the device:

---

[125] Thomson Reuters StreetEvents, Edited Transcript, PHIA.AS – Q4 2016 Koninklike Philips NV Earnings Call (Jan. 24, 2017), available at: http://www.philips.com/static/qr/2016/q4/philips-fourth-quarter-results-2016-transcript.pdf (last accessed Oct. 3, 2022) (attached hereto as Exhibit "61"), at 5.

[126] *See* Royal Philips Press Release, Philips expands its award-winning DreamStation platform to treat patients with most complex sleep and breathing needs (Mar. 7, 2017), https://www.prnewswire.com/news-releases/philips-expands-its-award-winning-dreamstation-platform-to-treat-patients-with-most-complex-sleep-and-breathing-needs-300418735.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "62").

[127] *See* Royal Philips Press Release, Philips Simplifies Travel for Sleep Apnea Patients with New Compact and Connected DreamStation Go Sleep Therapy Device (Apr. 11, 2017), https://www.philips.com/a-w/about/news/archive/standard/news/press/2017/20170411-philips-simplifies-travel-for-sleep-apnea-patients-with-new-compact-and-connected-dreamstation-go-sleep-therapy-device.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "63").

[128] *Id.*

[129] *See* Royal Philips webpage for Abhijit Bhattacharya, https://www.philips.com/a-w/about/executive-committee/abhijit-bhattacharya.html (last accessed Oct. 10, 2022) (attached hereto as Exhibit "64"). Mr. Bhattacharya is based in Eindhoven, the Netherlands. *Id.*

> As Frans [van Houten] mentioned, in Health & Wellness, we have a solid pipeline of new product introductions . . . We will also launch the Philips DreamStation Go portable CPAP solutions. We will back these launches with the requisite support in advertising and promotion, which will have a dampening effect on the results of Personal Health in the second quarter. However, I hasten to add that we do expect to have continued improvements in operating results for Personal Health.[130]

172. On September 8, 2017, Royal Philips issued a press release announcing that, "At the European Respiratory Society (ERS) International Congress 2017 in Milan, Italy (September 9-13), Royal Philips (NYSE: PHG, AEX: PHIA), a global leader in health technology, will showcase and announce the global expansion of its suite of cutting-edge connected respiratory and sleep solutions," which included "the brand-new DreamStation Go," and the "DreamStation BiPAP AutoSV and AVAPS solutions."[131]

173. On November 13, 2017, Royal Philips issued a press release announcing that "Royal Philips" would be showcasing several new medical products, including the DreamStation Go, at the 2017 MEDICA World Forum for Medicine in Düsseldorf, Germany.[132] The press release quoted Frans van Houten as stating that "[t]he intelligent sleep therapy, respiratory care and ultrasound solutions we are showcasing at this year's MEDICA bridge important transitions from healthy living to diagnosis, and clinical treatment to home care and chronic disease management,

---

[130] Thomson Reuters StreetEvents, Edited Transcript, PHIA.AS – Q1 2017 Koninklike Philips NV Earnings Call (Apr. 24, 2017) (Exhibit "52" hereto), at 5.

[131] *See* Royal Philips Press Release, Philips showcases expanding connected respiratory and sleep solutions at ERS 2017 (Sept. 8, 2017), https://www.philips.com/a-w/about/news/archive/standard/news/press/2017/20170908-philips-showcases-expanding-connected-respiratory-and-sleep-solutions-at-ers-2017.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "65").

[132] *See* Royal Philips Press Release, Philips innovations at MEDICA 2017 connect people,technology and data across the health continuum (Nov. 13, 2017), https://www.philips.com/a-w/about/news/archive/standard/news/press/2017/20171113-philips-innovations-at-medica-2017-connect-people-technology-and-data-across-the-health-continuum.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "66").

allowing patients to return home and enjoy the most out of life as quickly as possible."[133] As with other similar press releases, Royal Philips' Elena Calamo Specchia was listed as the media contact.[134]

174. On November 14, 2017, Royal Philips issued a press release promoting its involvement in World COPD Day.[135] The press release also promoted the DreamStation Advanced Therapies products and the Trilogy hospital-to-home ventilators.[136] Royal Philips' Elena Calamo Specchia is again listed as the media contact.[137]

175. On January 29, 2018, Royal Philips issued a press release announcing that "Royal Philips" was participating in the 2018 Arab Health Exhibition and Congress on January 29, 2018 through February 1, 2018, and was showcasing several Philips products, including the DreamStation Go.[138] The press release directed media inquiries to Netherlands-based Joost Maltha,[139] as Royal Philips' Senior Global Press Officer, Director of Communications.[140]

---

[133] *Id.*

[134] *Id.*

[135] *See* Royal Philips Press Release, Philips launches global education and empowerment effort for World COPD Day (Nov. 14, 2017), https://www.philips.com/a-w/about/news/archive/standard/news/press/2017/20171114-philips-launches-global-education-and-empowerment-effort-for-world-copd-day.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "67").

[136] *Id.*

[137] *Id.*

[138] *See* Royal Philips Press Release, Philips Breaks Health Technology Boundaries at Arab Health 2018 (Jan. 29, 2018), https://www.philips.com/a-w/about/news/archive/standard/news/press/2018/20180129-philips-breaks-health-technology-boundaries-at-arab-health-2018.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "68").

[139] *Id.*

[140] *See* LinkedIn Profile for Joost Maltha (Sept. 29, 2022), https://nl.linkedin.com/in/joostmaltha (last accessed Oct. 3, 2022) (attached hereto as Exhibit "69").

176. On April 16, 2019, Royal Philips issued a press release announcing that Philips would be promoting "its latest offerings" at the Medtrade show in Las Vegas, Nevada in the Spring of 2019.[141] Philips featured its "new, patient-focused DreamStation Go Heated Humidifier and DreamWisp" "designed to further enhance effective and efficient care for patients with chronic respiratory and sleep conditions."[142]

177. In addition, from as early as September 2014 until the present, Royal Philips has maintained the website SleepApnea.com, which educates consumers and providers on sleep apnea and the various treatment devices offered by Philips.[143]

2. Philips Obtained Clearances For the Recalled Devices.

178. Philips obtained 510(k) clearance from the Food and Drug Administration ("FDA") for various CPAP, BIPAP and ventilator devices.

179. 510(k) clearance generally only requires the manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

---

[141] *See* Royal Philips Press Release, Philips showcases new opportunities for Home Medical Equipment providers at Medtrade Spring (Apr. 16, 2019), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2019/20190416-philips-showcases-new-opportunities-for-home-medical-equipment-providers-at-medtrade-spring.html (last accessed Oct. 9, 2022) (attached hereto as Exhibit "70").

[142] *Id.*

[143] *See* sleepapnea.com landing page, archived on Sept. 28, 2014 at https://web.archive.org/web/20140928073021/http://www.sleepapnea.com/ (last accessed Oct. 3, 2022) (attached hereto as Exhibit "71"). The landing page of the website contains a copyright for Royal Philips: "© Koninklijke Philips N.V., 2004 - 2014. All rights reserved.)."

180. Philips utilized the 510(k) process to receive clearances for each of its Recalled Devices except the E30 ventilator which was marketed under an Emergency Use Authorization ("EUA").

181. With respect to the EUA for the E30 ventilator, on March 24, 2020, in response to "concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in healthcare settings to treat patients during the Coronavirus Disease 2019 (COVID-19) pandemic,"[144] the FDA issued an umbrella EUA of ventilators and related equipment. On April 8, 2020, this EUA was extended to the E30 ventilator.[145] A device may be authorized under this umbrella EUA if it "may be effective" in diagnosing, treating, or preventing COVID-19[146]; and according to the FDA, "[t]he 'may be effective' standard for EUAs provides for a lower level of evidence than the 'effectiveness' standard that FDA uses for product approvals."

182. With respect to the 510(k) process for each of the other Recalled Devices, Philips included data, testing, and biocompatibility results along with its applications to claim substantial equivalence to a predicate device.

183. Upon reviewing the submissions, the FDA determined Philips' devices were substantially equivalent to a predicate device.

184. After the devices were sold, Philips had a duty to find, investigate, and report adverse events to the FDA. For example, 21 C.F.R. part 803 requires Philips to conduct a thorough

---

[144] *See* Food and Drug Administration, Ventilators and Ventilator Accessories EUAs, https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas (last accessed Oct. 3, 2022).

[145] *Id.*

[146] *See* Food and Drug Administration, Emergency Use Authorization Letter (Mar. 24, 2020), available at: https://www.fda.gov/media/136423/download (last accessed Oct. 3, 2022) (attached hereto as Exhibit "143").

investigation of each event. This duty is triggered when Philips becomes aware of information from any source that reasonably suggests that its device (1) may have caused or contributed to a death or serious injury, or (2) has malfunctioned, and, this device or a similar device it markets, is likely to cause or contribute to a death or serious injury, if the malfunction were to recur. 21 C.F.R. § 803.50.

185. Additionally, as a manufacturer, Philips has unique knowledge concerning the frequency, severity and predictability of the complications and risks associated with its devices. Accordingly, Philips has post-market responsibility under the FDA Regulations related to complaint handling, investigation and reporting to the FDA, including but not limited to:

a. 21 C.F.R. § 803.10 (for example, § 803.10(c) requires adverse events to be reported by a manufacturer in set time frames from 5 to 30 days when the event becomes known);

b. 21 C.F.R. § 803.17 ("Medical device manufacturers must develop and implement standardized medical device reporting procedures so that timely evaluation of events and communication of findings can occur.");

c. 21 C.F.R. § 803.18 (§ 803.18(d)(1) requires a device distributor to maintain complaint files and records, including any written, electronic or oral communication, either received or generated by the distributor, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device.);

d. 21 C.F.R. § 803.20 ("Manufacturers must timely communicate a reportable event. Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.");

e. 21 C.F.R. § 803.3 ("If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory

responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.");

f. 21 C.F.R. § 803.50 ((a) "If you are a manufacturer, you must report to the FDA information required by 803.52 in accordance with the requirements of 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." Subsection (b) defines information reasonably known to a manufacturer to include: "[a]ny information that you can obtain by contacting a user facility, importer, or other initial reporter; . . . [a]ny information in your possession; or . . . [a]ny information that you can obtain by analysis, testing, or other evaluation of the device." Section 803.50 continues: "(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56 in accordance with the requirements of 803.12(a).");

g. 21 C.F.R. § 803.52 (detailed individual and device information must be submitted for each adverse event);

h. 21 C.F.R. § 803.53 (information regarding detailed individual and device information must be submitted in a timely manner when remedial action may be required);

i. 21 C.F.R. § 803.56 (supplemental reporting must be done if additional information is learned that became known after the initial report was submitted); and

j. 21 C.F.R. § 820.198 ("Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether

> the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event").

186. In addition, there are state law duties to monitor, investigate, evaluate and timely report injuries and other important safety information regarding a medical device, which Philips violated when it failed to: monitor, investigate and report PE-PUR foam degradation risk and incidents; take the necessary steps to continually evaluate the safety, effectiveness and reliability of its Recalled Devices; and take necessary steps to warn, strengthen its warnings, and take other measures to assure compliance with its obligations.

3. The Recalled Devices Are "Adulterated" According To The FDA's Findings And, Therefore, They Are Worthless.

187. The FDA determined that the Recalled Devices failed to comply with "current good manufacturing practice" requirements ("GMPs") codified in FDA regulations.[147] Devices that are not manufactured in compliance with FDA's GMPs "shall be deemed adulterated." 21 U.S.C. § 351(h); *see id.* § 360j(f)(1) (authorizing FDA to issue regulations prescribing GMP requirements). Title 21 of the U.S. Code prohibits the sale, receipt, or delivery of "adulterated" devices. *See* 21 U.S.C. § 331(a) & (c). Accordingly, the Recalled Devices were adulterated and prohibited for sale, receipt, or delivery.

188. Specifically, the FDA determined that Philips' manufacture of the Recalled Devices failed to comply with the GMPs imposed by FDA's "Quality System Regulation" ("QSR") "since at least November 2015."[148] The QSR required Philips to "establish and maintain

---

[147] *See* Food and Drug Administration 518(b) Notice Letter to Philips Respironics, May 2, 2022 (hereinafter "518(b) Notice"), available for download at https://www.fda.gov/media/158129/download (attached hereto as Exhibit "72"), at 6 (citing 21 CFR § 820.100).

[148] *Id.* at 6, 10.

procedures for implementing corrective and preventative action" for the Recalled Devices that satisfy seven criteria. 21 C.F.R. § 820.100(a)(1)-(7).

189. In addition to the FDA's determination that the Recalled Devices violated the QSR requirements codified at 21 C.F.R. § 820.100, the Recalled Devices were "adulterated," and their sale prohibited, under 21 U.S.C. § 351(c), which bans a device as adulterated if its "purity or quality falls below[] that which it purports or is represented to possess." 21 U.S.C. § 351(c).

190. There is no dispute that the Recalled Devices "fall[] below" their represented quality. *See* 21 U.S.C. § 351(c). Philips sold the Recalled Devices as, *inter alia*, "clinically proven" treatments for sleep disorders.[149] But in its Recall and elsewhere, Philips admits that their use may cause "serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."[150] As such, the Recalled Devices were undisputedly adulterated and unsalable pursuant to 21 U.S.C. § 351(c).

191. Further, the FDA's investigation revealed that Philips' incorporation of PE-PUR foam in the Recalled Devices at all times violated other subdivisions of the QSR, minimally including:

a. 21 C.F.R. § 820.70(h) (requiring manufacturers to "establish and maintain procedures for the use and removal of" manufacturing materials that "could reasonably be expected to have an adverse effect on product quality");

[149] *See, e.g.*, Philips US Product page, DreamStation BiPAP autoSV ("DreamStation BiPAP autoSV['s] . . . clinically proven algorithm provides support when needed."), https://www.usa.philips.com/healthcare/product/HCAHX900T15/dreamstation-bipap-autosv-servo-ventilation-system (last accessed Oct. 4, 2022) (attached hereto as Exhibit "73"); Philips US DreamStation Go - Features ("DreamStation Go includes the same clinically-proven Flex pressure-relief technologies, therapy algorithms and event detection found in our DreamStation and System One PAP therapy devices."), https://www.usa.philips.com/healthcare/product/HCEUG502S15/dreamstation-go-portable-pap-therapy-system#features (last accessed Oct. 5, 2022) (attached hereto as Exhibit "74").

[150] Philips Recall Notices issued June 14, 2021 (Exhibit "4" hereto).

b. 21 C.F.R. § 820.30(c) (requiring manufacturers to "establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device"); and

c. 21 C.F.R. § 820.30(g) (requiring manufacturers to "establish and maintain procedures for validating the device design," including "that devices conform to defined user needs and intended uses").

192. Philips' failure to comply with the FDA's QSR (and, concomitantly the FDA's GMPs) establishes that the Recalled Devices were "adulterated" and should not have been sold in the first instance. Each violation of the QSR furnishes an independent basis to find the Recalled Devices were "adulterated" within the meaning of Title 21. *See* 21 U.S.C. §§ 351(h) & 360j(f)(1).

193. Adulterated devices that put users at risk of life-threatening injuries, like the Recalled Devices here, are worthless because they can neither be demanded nor supplied: they cannot be legally sold, received, or delivered in interstate commerce. 21 U.S.C. § 331(a) & (c).

D. PE-PUR FOAM POSES SERIOUS HEALTH RISKS TO USERS OF PHILIPS DEVICES.

194. Philips has belatedly revealed that the PE-PUR foam in the Recalled Devices degrades and exposes patients to toxic particles and gases. Such exposure has harmed hundreds of thousands of patients across the United States who used the Recalled Devices.

195. Patients who used Recalled Devices, including all of the individual Plaintiffs, are now at risk of developing cancer and other serious health conditions in the future.

196. On the same day as the Recall – June 14, 2021 – Philips released an announcement entitled "Clinical information for physicians." In this announcement, Philips disclosed that it "has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[151] The PE-PUR foam is

[151] *See* Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical Information for physicians (June 14, 2021) (Exhibit "7" hereto), at 4.

black, and when it breaks down, it can release black particles.[152] The announcement stated that the foam breakdown "may lead to patient harm and impact clinical care,"[153] explaining:

> While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, ***it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.***[154]

197. The announcement mentioned two types of hazards from the foam in the devices: dangers from foam degradation and dangers from release of VOCs.

198. First, the announcement described dangers arising from foam degradation exposure:

> **Potential Hazard:** Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.
>
> The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
>
> - Toluene Diamine
>
> - Toluene Diisocyanate
>
> - Diethylene glycol.[155]

199. The inhalation of extremely fine particulates, even non-toxic particulates, can lead

---

[152] *Id.* at 3.

[153] *Id.* at 1.

[154] *Id.* at 2 (emphasis added).

[155] *Id.* at 3-4.

to adverse health outcomes. The Environmental Protection Agency ("EPA") notes that exposure to particles less than 10 micrometers can be linked to a variety of health problems including: aggravated asthma, decreased lung function, increased respiratory symptoms, and cardiac related diseases."[156]

200. On July 8, 2021, Philips released an update to a global supplemental clinical information document that contained results based on its own testing of the affected devices, stating that: "According to analysis performed by Philips, the majority of particulates are of a size (>8 μm) . . . Smaller particulates (<1-3 μm) are capable of diffusing into deep lung tissue and deposit into the alveoli. During testing performed by an outside laboratory on lab degraded foam, the smallest particulate size identified was 2.69 μm."[157]

201. The purity of the air coming from a breathing device to a patient is highly important and material. Indeed, Philips advertises the filtration systems in its devices, for example, noting them on a diagram in its DreamStation Family Brochure.[158] Philips' filtration system, however, does not filter out the particles described above.

202. In addition to the hazards created by the inhalation of extremely fine particulates, Philips has admitted that the particulates created via PE-PUR foam degradation contain toxic compounds such as toluene diamine, toluene diisocyanate, and diethylene glycol.[159] As discussed

---

[156] *See* Health and Environmental Effects of Particulate Matter (PM) | US EPA (last accessed Oct. 3, 2022) (attached hereto as Exhibit "75").

[157] *See* Royal Philips Informational PDF, Sleep and Respiratory Care update, Clinical Information (July 8, 2021), available at: philips-global-supplemental-clinical-information-document.pdf (last accessed Oct. 3, 2022) (attached hereto as Exhibit "76"), at 2.

[158] *See* Philips Respironics DreamStation Family Brochure, available at: https://www.documents.philips.com/assets/20180205/15ef65ad106d4ddc88fca87e0134dc60.pdf (last accessed Oct. 9, 2022) (attached hereto as Exhibit "77").

[159] *See* Royal Philips Informational PDF, Sleep and Respiratory Care update, Clinical Information (July 8, 2021) (Exhibit "76" hereto), at 1.

in more detail below, these compounds are toxic and/or carcinogenic when inhaled or ingested.

203. Philips concluded in its Health Hazard Evaluations ("HHEs") regarding the PE-PUR foam degradation risk that "[b]ased on the cytotoxicity and genotoxicity results and toxicological risk assessment, combined with [the] conclusion that particles are likely to reach the upper airway and potentially the lower respiratory track [*sic*], a reasonable worst-case estimate for the general and higher risk (e.g., patient populations with preexisting conditions or comorbidities) patient populations is a severity level 3 (Crucial) for both short/intermediate and long term exposure."[160]

204. [redacted]

205. Further, [redacted]

206. Philips' HHEs note that the harm due to foam degradation "'may not be immediately recognizable and may not be something that the customer would/could report,' adding that certain harms 'may not be easily linked to the hazardous situation or device use in general'—

[160] 518 (b) Notice (Exhibit "72" hereto), at 3-4.

[161] [redacted]

[162] [redacted]

and that in the case of genetic mutations in particular, 'a presumed lag time from exposure to harm development may make it difficult for patients to attribute their individual harm to the device usage.'"[163]

207. The second hazard is the release of VOCs, that is, toxic and carcinogenic chemical emissions from the PE-PUR foam. Philips explained:

> **Potential Hazard:** Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.
>
> Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:
>
> - Dimethyl Diazine
>
> - Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl).[164]

208. In addition to these two compounds, Philips has also found high levels of formaldehyde, a known carcinogen, in analyses of the Recalled Devices. Collectively, these compounds released by PE-PUR foam—formaldehyde, toluene diamine, toluene diisocyanate, diethylene glycol, dimethyl diazine, and phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)—are referred to herein as the "Foam Toxins."

209. Philips admitted that the risks of these VOCs include: "irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and

[163] 518 (b) Notice (Exhibit "72" hereto), *Id.* at 5.

[164] *See* Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical Information for physicians (June 14, 2021) (Exhibit "7" hereto), at 4-5.

carcinogenic effects," as well as "adverse effects to other organs" such as kidney and liver.[165]

210. It is beyond reasonable dispute that patients using the Recalled Devices were exposed to harmful particulates and the toxic Foam Toxins. As detailed below, each of the Foam Toxins poses a serious health hazard to users of the Recalled Devices.

1. Formaldehyde Is A Known Carcinogen.

211. Although Philips has not publicly acknowledged that formaldehyde is used in the manufacturing process for PE-PUR foam or is a byproduct of PE-PUR foam degradation, Philips' internal testing (dated May 22, 2019) reported the presence of formaldehyde in analyses of its DreamStation 1 devices, finding "tolerable limits of the Formaldehyde compound were exceeded during initial operation, as well as at the [redacted]."[166]

212. Formaldehyde is a proven hazardous substance. Among other hazards, Formaldehyde has been classified as carcinogenic to humans (Group 1)[167] by the International Agency for Research on Cancer ("IARC") since 2006.[168] Governmental authorities in the United States have reached similar conclusions: the National Toxicology Program in the United State

---

[165] *Id.* at 4, 5.

[166] *See* 483 Report (Exhibit "5" hereto), at 6.

[167] The IARC, an agency of the World Health Organization, groups carcinogenic and potentially carcinogenic substances into five categories: Group 1, carcinogenic to humans; Group 2A, probably carcinogenic to humans; Group 2B, possibly carcinogenic to humans; Group 3, not classifiable as to its carcinogeneity to humans; and Group 4, probably not carcinogenic to humans. International Agency for Research on Cancer, *Agents Classified by the IARC Monographs, Volumes 1–129*, IARC (last updated July 1, 2022), available at: http://monographs.iarc.fr/ENG/Classification/index.php (last accessed Oct. 3, 2022). The EPA uses an equivalent grouping system of five categories (Groups A-E). *See Risk Assessment for Carcinogenic Effects*, EPA.com, available at: https://www.epa.gov/fera/risk-assessment-carcinogenic-effects (last accessed Oct. 3, 2022).

[168] *Formaldehyde*, IARC Monograph – 100F, IARC, available at: https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono100F-29.pdf (last accessed Oct. 3, 2022).

Department of Health and Human Services ("NTP") has classified formaldehyde as a known human carcinogen since 2011[169]; and the EPA has considered formaldehyde to be a probable human carcinogen (Group B1) since 1989.[170]

213. There is extensive research, including dozens of human epidemiological studies, showing an association between formaldehyde exposure and numerous forms of cancer, including: nasopharyngeal cancer; sinonasal cancer; leukemia; lung cancer; lymphohematopoietic cancers (other than leukemia); nasal, oral, and throat cancers (other than nasopharyngeal and sinonasal cancers); brain cancer; hepatic cancer; esophageal cancer; thyroid cancer; and pancreatic cancer.[171] Additionally, exposure to formaldehyde appears to have a strong causal relationship to asthma.[172]

2. Toluene Diisocyanate Is A Likely Carcinogen.

214. Toluene diisocyanates ("TDI") are used primarily to manufacture flexible polyurethane foams such as PE-PUR foam. Philips has recognized that PE-PUR foam releases TDIs as it degrades.[173]

---

169 *Formaldehyde*, Report on Carcinogens, NTP, available at: https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf (last accessed Oct. 3, 2022).

170 *See* https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet#r1 (last accessed Oct. 3, 2022).

171 *See, e.g.*, *Formaldehyde*, Report on Carcinogens, NTP, available at: https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf; *1910.1048 App C - Medical surveillance – Formaldehyde*, OSHA.com, available at: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1048AppC (last accessed Oct. 3, 2022).

172 *See, e.g., 1910.1048 App C - Medical surveillance – Formaldehyde*, OSHA.com, available at: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1048AppC (last accessed Oct. 3, 2022).

173 *See* Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical information for physicians (June 14, 2021) (Exhibit "7" hereto), at 4; Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical Information (July 8, 2021) (Exhibit "76" hereto), at 1 ("[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include … toluene diisocyanate isomers (TDI)").

215. TDI is a proven hazardous substance. Among other hazards, TDI is classified as possibly carcinogenic to humans (Group 2B) by IARC.[174] The United States Center for Disease Control ("CDC"), Occupational Safety and Health Administration ("OSHA"), and National Institute for Occupational Safety and Health ("NIOSH") also regard TDI as a potential human carcinogen based on tumorigenic responses in TDI treated rats and mice.[175] The EPA has taken action under the Toxic Substances Control Act to allow oversight of the use of TDI in consumer products.[176] NTP classifies TDI as "reasonably anticipated to be a human carcinogen" based on sufficient evidence of carcinogenicity from studies in experimental animals.[177] The European Union warns that TDI "is fatal if inhaled."[178]

216. Administration of TDI by stomach tube caused liver tumors (hepatocellular adenoma) in female rats and mice, benign tumors of the mammary gland (fibroadenoma) and pancreas (islet-cell adenoma) in female rats, and benign tumors of the pancreas (acinar-cell adenoma) in male rats. It also increased the combined incidences of benign and malignant tumors of subcutaneous tissue (fibroma and fibrosarcoma) in rats of both sexes and of the blood vessels

---

[174] *Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, available for download at https://publications.iarc.fr/_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf (last accessed Oct. 3, 2022).

[175] *See, e.g.*, *Toluene diisocyanates*, Report on Carcinogens, NTP, available at: https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf (last accessed Oct. 3, 2022); *Current Intelligence Bulletin 53, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, NIOSH Pub. No. 90-101 (Dec. 1989), available at: https://www.cdc.gov/niosh/docs/90-101/default.html (last accessed Oct. 3, 2022).

[176] *See* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-toluene-diisocyanate-tdi-and-related#action (last accessed Oct. 3, 2022).

[177] *See* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf (last accessed Oct. 3, 2022).

[178] https://echa.europa.eu/substance-information/-/substanceinfo/100.043.369 (last accessed Oct. 3, 2022).

(hemangioma and hemangiosarcoma) in female mice.[179] Exposure to TDI also has been documented to cause respiratory irritation, asthma, and lung damage.[180]

3. Toluene Diamine Is A Likely Carcinogen.

217. Philips has recognized that PE-PUR foam releases toluene diamine ("TDA") as it degrades.[181] Additionally, TDA is a hydrolysis product of TDI.

218. TDA is a proven hazardous substance. Among other hazards, IARC has classified TDA as possibly carcinogenic to humans (Group 2B),[182] and the EPA classifies it as a probable human carcinogen.[183] The European Union has concluded that TDA "cannot be considered safe for use" even as a hair dye, let alone breathed into the lungs for many hours each night.[184] The NTP classifies TDA as reasonably anticipated to be a human carcinogen based on animal studies.[185]

219. Available data on TDA primarily comes from animal studies. These studies

---

[179] *See* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf. (last accessed Oct. 3, 2022).

[180] *See, e.g.*, *Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, available for download at https://publications.iarc.fr/_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf (last accessed Oct. 3, 2022).

[181] *See* Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical Information (July 8, 2021) (Exhibit "76" hereto), at 1 ("[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include … toluene diamine isomers (TDA)").

[182] *See Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, available for download at https://publications.iarc.fr/_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf (last accessed Oct. 3, 2022).

[183] *See Toluene 2,4 diamine*, EPA (Jan. 2000), available at: https://www.epa.gov/sites/default/files/2016-09/documents/toluene-2-4-diamine.pdf (last accessed Oct. 3, 2022).

[184] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_093.pdf (last accessed Oct. 3, 2022), at 5.

[185] *2,4-Diaminotoluene*, Report on Carcinogens, NTP, available at: https://ntp.niehs.nih.gov/ntp/roc/content/profiles/diaminotoluene.pdf (last accessed Oct. 3, 2022).

strongly support an association between TDA and hepatic cancer.[186] There is evidence of a link between TDA exposure and pulmonary fibrosis based on in vitro studies in which human lung fibroblasts were exposed to TDI and TDA.[187] The EPA has determined that acute exposure to TDA can produce severe skin and eye irritation, sometimes leading to permanent blindness, respiratory problems (*e.g.*, asthma), rise in blood pressure, dizziness, convulsions, fainting, and coma.[188] Exposure to TDA can also cause irritation of the skin, nose, and throat, damage to reproductive and neurological systems, eye irritation, dermatitis, ataxia, tachycardia, respiratory depression, stomach gas, hypertension, nausea, vomiting, methemoglobinemia, cyanosis, headache, weakness, exhaustion, dizziness, convulsions, fainting, and coma.[189]

4. Diethylene Glycol Is Toxic To Humans.

220. Diethylene glycol ("DEG") is a widely used solvent. It is a colorless and odorless liquid with a sweetish taste and has often been a contaminant in consumer products, resulting in numerous epidemics of poisoning. DEG is used in the production of polyester polyurethane foam,

[186] *Id.*

[187] It is well established that TDI is converted to TDA through hydrolysis (a reaction caused by exposure to water). *See Current Intelligence Bulletin 53, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, NIOSH Pub. No. 90-101 (Dec. 1989), available at: https://www.cdc.gov/niosh/docs/90-101/default.html (last accessed Oct. 3, 2022). Thus, ingested TDI may react with saliva and/or gastrointestinal fluids and convert to TDA. Additionally, there is evidence that inhaled TDI is converted into TDA by reaction with a substance (gluthathione) present in the lungs. As a result, observed effects ascribed to TDI may be due to unmeasured conversion to TDA after exposure.

[188] *Id.*

[189] *See Toluene 2,4 diamine*, EPA (Jan. 2000), available at: https://www.epa.gov/sites/default/files/2016-09/documents/toluene-2-4-diamine.pdf (last accessed Oct. 3, 2022).

and Philips has admitted that DEG is a byproduct of PE-PUR foam degradation.[190]

221. DEG is a proven hazardous substance. Among other hazards, DEG has a historical involvement in mass poisonings around the world. Famously, DEG caused the death of 100 people across 15 states in the 1937 Elixir Sulfanilamide Incident, which served as a catalyst for the enactment of the Federal Food, Drug, and Cosmetic Act ("FDCA") in 1938.[191]

222. DEG is a toxic substance with a mean fatal dose of 1 mL/kg of pure DEG.[192] Ingesting only a small amount may result in gastrointestinal distress and stupor.[193] Exposure may cause irritation of the eyes, skin, and mucous membranes.[194] DEG has also been shown to have damaging toxic, irritating, and inflammatory properties when inhaled.[195]

5. Dimethyl Diazine Is A Precursor To A Known Carcinogen.

223. Dimethyl diazene ("DD"), also known as azomethane, is "associated with the production process of the [PE-PUR] foam."[196] Philips has admitted that DD is emitted from PE-

[190] *See* Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical Information (July 8, 2021) (Exhibit "76" hereto), at 1 ("[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include diethylene glycol (DEG) ….").

[191] https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf (last accessed Oct. 3, 2022).

[192] L.J. Schep, *et al*., *Diethylene glycol poisoning*, Clin. Toxicol. 47(6):525-35 (July 2009).

[193] *See Ethylene Glycol: Systemic Agent*, NIOSH, available at: https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750031.html (last accessed Oct. 9, 2022).

[194] *Id.*

[195] *See, e.g.*, C.J. Hardy, *et al.*, *Twenty-eight-day repeated-dose inhalation exposure of rats to diethylene glycol monoethyl ether*, Fundam. Appl. Toxicol. 38(2):143-7 (Aug. 1997).

[196] *See* Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical Information (July 8, 2021) (Exhibit "76" hereto), at 3 (finding that during "testing which ran a device at 35°C ± 2°C for 168 hours, two compounds of concern were emitted from the device: dimethyl diazene and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)").

PUR foam under normal conditions and possibly also as the result of degradation.[197]

224. DD is a member of a family of chemicals that are proven hazardous substances. While IARC has not yet evaluated the potential carcinogenicity of DD to humans, as there is scant data concerning the effects of DD on humans and animals. However, DD is a member of a family of carcinogenic substances: 1,2-dimethylhydrazine (a Group 2A probable human carcinogen that exhibits hepatotoxic effects along with injuries to other organs in animal experiments[198]) dehydrogenates into DD, which then oxidizes into azoxymethane (a known carcinogen that has not yet been classified by the EPA or IARC). Azoxymethane further oxidizes into methylazoxymethanol, a Group 2B possible human carcinogen.[199] Both methylazoxymethanol and 1,2-dimethylhydrazine have been found to metabolize into formaldehyde, a Group 1 known carcinogen.[200] Thus, an individual regularly exposed to DD may also have been exposed to 1,2-dimethylhydrazine, azoxymethane, methylazoxymethanol, and/or formaldehyde—each of which

---

[197] *Id.*

[198] G. Choudary, *Toxicological Profile for Hydrazines*, Agency for Toxic Substances and Disease Registry (1997); R.B. Wilson, *Species variation in response to dimethylhydrazine, Toxicology and Applied Pharmacology*, 38:3 (1976); M.A. Bedell, *et al*., *Cell Specificity in Hepatocarcinogenesis: Preferential Accumulation of O6 Methylguanine in Target Cell DNA during Continuous Exposure of Rats to 1,2-Dimethylhydrazine*, Cancer Res 42:3079-3083 (1982); W.J. Visek, *et al*., *Dietary protein and chronic toxicity of 1,2-dimethylhydrazine fed to mice*, Journal of Toxicology and Environmental Health, 32:4, 383-413 (1991).

[199] E. Fiala, *Investigations into the metabolism and mode of action of the colon carcinogen 1, 2-dimethylhydrazine,* Cancer, 36:2407-12 (Dec. 1975); S. Wolter, N. Frank, *Metabolism of 1,2-dimethylhydrazine in isolated perfused rat liver*, Chemico-Biological Interactions, 42:3, 335-344 (1982); IARC Monograph – 71-42, IARC (1987); IARC Monograph Supplement 7, IARC (1987); H. Druckrey, *Production of colonic carcinomas by 1,2-dialkylhydrazines and azoxyalkanes*, Carcinoma of the Colon and Antecedent Epithelium 267-279 (1970).

[200] P. Harbach, *et al*., *Effects of selenium on 1,2-dimethylshydrazine metabolism and DNA alkylation* (1981); S.N. Newaz, *et al*., *Metabolism of the Carcinogen 1,2Dimethylhydrazine by Isolated Human Colon Microsomes and Human Colon Tumor Cells in Culture* (1983); J. Erikson, *et al*., *Oxidative Metabolism of Some Hydrazine Derivatives by Rat Liver and Lung Tissue Fractions* (1986).

is recognized as a known or probable carcinogen—as these compounds are oxidized and metabolized.

225. DD is clearly linked to colorectal cancer in mice. Azoxymethane, the product of oxidized DD, is used to induce colorectal cancer in animals and has been shown to cause hepatic lesions, intestinal tumors, and renal tumors.[201] Oxidized azoxymethane produces methylazoxymethanol, which is known to cause DNA damage and has been associated with amyotropic lateral sclerosis, parkinsonism, dementia, colon cancer, liver cancer, and prostate cancer.[202] Exposure to DD—as the precursor to these carcinogenic compounds—means exposure to these other compounds and the health risks they pose.

6. Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) Is A Toxic Compound.

226. Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl) ("DTBSBP") is "associated with the production process of the foam."[203] According to Philips, DTBSBP is emitted from PE-PUR foam under normal conditions and possibly also as the result of degradation.[204]

227. DTBSBP is a proven hazardous substance. Among other hazards, in 2010, the Canadian government determined that DTBSBP was a Schedule 1 toxic substance under the Canadian Environmental Protection Act "based on available information regarding possible

[201] M. Kobaek-Larsen, *et al*., *Secondary effects induced by the colon carcinogen azoxymethane in BDIX rats*, APMIS 112(6):319-29 (2004 June).

[202] P. Spencer, *et al*., *Unraveling 50-Year-Old Clues Linking Neurodegeneration and Cancer to Cycad Toxins: Are microRNAs Common Mediators?*, Frontiers in Genetics 3 (2012).

[203] *See* Royal Philips Informational PDF, Sleep and Respiratory Care Update: Clinical Information (July 8, 2021) (Exhibit "76" hereto), at 3 (finding that during "testing which ran a device at 35°C ± 2°C for 168 hours, two compounds of concern were emitted from the device: dimethyl diazene and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)").

[204] *Id.*

persistence, accumulation in organisms and potential to cause harm to organisms."[205] These findings prompted Canadian regulators to propose "virtual elimination" of DTBSBP.[206]

E. PHILIPS KNEW OF THE DANGERS OF PE-PUR FOAM FOR MANY YEARS PRIOR TO THE RECALL

228. At the time it installed PE-PUR foam into the Recalled Devices, Philips was required to test the devices in accordance with various international standards, including ISO 18562-2:2017, ISO 18562-3:2017, ISO 10993-13, and ISO 10993-9.

229. At that time, Philips should have known the PE-PUR foam posed a safety risk to users.

230. The FDA concluded after an investigation of Philips' Recalled Devices that beginning in at least 2008, and over time, Philips received hundreds of thousands of customer complaints regarding foam degradation in the Recalled Devices and, years later, received data from a variety of sources confirming foam degradation.

231. The FDA's findings were based, in part, on twenty-one (21) site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021 and November 9, 2021. The lead FDA investigator, Katelyn A. Staub-Zamperini, memorialized the agency's findings in a 29-page FDA 483 Report issued on November 9, 2021.[207] The FDA delivered the 483 Report to Rodney Mell, Head of Quality at Philips Respironics, on or around November 9, 2021.[208]

---

[205] *Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)- (DTBSBP)*, Government of Canada, Canada.ca, available at: https://www.canada.ca/en/health-canada/services/chemical-substances/challenge/batch-8/1-methylpropyl.html. (last accessed Oct. 3, 2022).

[206] *Id.*

[207] *See generally*, 483 Report (Exhibit "5" hereto).

[208] *Id.* at 1, 29.

232. A 483 Report "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts."[209] These observations are made in a 483 Report "when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been . . . or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."[210]

233. In connection with the FDA's investigation for its 483 Report, the FDA learned that Philips received hundreds of thousands of complaints from customers about degradation of the foam in its Recalled Devices beginning at least as early as 2008:

> [A] query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, **resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices**. Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that **30 Trilogy related complaints were received from 2014 to 2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021**.[211]

234. Yet, "[n]o formal investigation, risk analysis, or CAPA were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017 . . . ."[212]

235. A Corrective and Preventative Action ("CAPA") refers to procedures that medical device manufactures must follow to identify and attempt to correct a quality problem after one is detected. *See* 21 C.F.R. § 820.100. A CAPA is designed "to collect information, analyze

---

[209] *See* FDA Form 483 Frequently Asked Questions (Exhibit "6" hereto).

[210] *Id.*

[211] 483 Report (Exhibit "5" hereto), at 12 (emphasis added).

[212] *Id.* at 16.

information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence."[213]

236. The FDA also found that Philips "was made aware of polyester polyurethane [PE-PUR] foam degradation issues in/around October 2015 . . . ."[214] [redacted]

237. In fact, an adverse event report from the FDA Manufacturer and User Facility Device Experience ("MAUDE") database shows that, as early as 2011, Philips knew that a patient discovered "black dust" on her nose when she awoke after using a Philips RemStar CPAP device and subsequently underwent treatment for "intoxication" and "chest tightness."[216]

238. Philips investigated this report and confirmed that the device contained "evidence of an unk[nown] black substance in the air path and on internal components . . . present throughout both the intake and exhaust portions of the air path . . . ."[217]

---

[213] *See* Food and Drug Administration, Corrective and Preventative Actions (CAPA), https://www.fda.gov/corrective-and-preventive-actions-capahttps://www.fda.gov/corrective-and-preventive-actions-capa (last accessed Oct. 3, 2022).

[214] 483 Report (Exhibit "5" hereto), at 18.

[215] [redacted]

[216] MAUDE Adverse Event Report: RESPIRONICS, INC. REMSTAR PRO INTERNATIONAL, http://www.fdable.com/advanced_maude_query/324fd08a137ce36c2d5faf453ee26f2f (last accessed Oct. 3, 2022).

[217] *Id.*

239. The FDA found that Philips' analysis of consumer complaints was itself defective in that it "was not adequately performed to identify or detect quality problems."[218] The FDA concluded that "potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation's instructions."[219] In light of this, the FDA concluded that Philips' "risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware" of these issues.[220]

240. Company documents show that [redacted]

241. [redacted]

[218] 483 Report (Exhibit "5" hereto), at 16.

[219] *Id.* at 13.

[220] *Id.* at 3.

[221] [redacted]

[222] [redacted]

[223] [redacted]

[redacted]

242. Indeed, [redacted]

243. The FDA has concluded that:

> Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.[227]

244. The FDA 483 Report notes that "an incorrect and non-specified polyester polyurethane, raw foam product, sourced from your [Philips'] raw foam supplier resulted in [redacted] non-conforming Trilogy Evo ventilatory finished devices being approved, released, and

[224] [redacted]

[225] [redacted]

[226] [redacted]

[227] 518(b) Notice (Exhibit "72" hereto), at 6.

distributed, which further resulted in the ongoing correction and removal."[228] The correction and removal "were established as part of [Philips'] response to failed VOC and ISO 18562 testing of related Trilogy EVO ventilatory medical devices … which resulted from the presence of the non-specified polyester polyurethane foam component, incorrectly supplied by [Philips'] raw foam supplier."[229]

245. Company documents show that from at least as early as 2016, Royal Philips has demonstrated a systematic level of involvement in and control over testing the PE-PUR foam in the Recalled Devices and investigating the problems with that foam.

246. For example, there is evidence that [redacted]

247. In addition, [redacted]

[228] 483 Report (Exhibit "5" hereto), at 25.

[229] *Id.*

[230] [redacted]

[231] [redacted]

[232] [redacted]

[redacted]

248. Philips explains that "Innovation & Strategy advances innovation together with Philips' businesses, markets and partners. This entails cooperation between research, design, medical affairs, professional services, marketing, strategy and businesses in a multi-disciplinary fashion, from early exploration to first-of-a-kind offerings."[237] The I&S Hub is also responsible for providing engineering solutions to all of Philips businesses, which is "accountable for bringing engineering capabilities in Philips to world-class level to realize innovations that deliver on our customers' needs. . .Taking a customer-first approach, Engineering Solutions turns ideas into working innovations by providing deep engineering expertise, cross-business product platforms,

[233] [redacted]

[234] [redacted]

[235] [redacted] *see also* Royal Philips 2020 SEC Form 20-F filing, Exhibit 8 (Exhibit "16" hereto). [redacted]

[236] [redacted]

[237] *See* Royal Philips 2021 Annual Report (Exhibit "13" hereto), at 21.

and innovation processes and tools. Engineering Solutions also works for selected external companies in the healthcare, high-tech and semiconductor industries."[238]

249. Additionally, "The role of Innovation & Strategy is to listen to the voice of the customer and, in collaboration with the operating businesses and the markets, direct the company strategy and innovation roadmap to achieve our growth and profitability ambitions. The various components of Innovation & Strategy include: the Chief Technology Office (CTO), Research, HealthSuite Platform, the Chief Medical Office, Engineering Solutions, Experience Design, Healthcare Transformation Services, Strategy, and Partnerships. Our four largest Innovation Hubs are in Eindhoven (Netherlands), Cambridge (USA), Bangalore (India) and Shanghai (China)."[239] While the Hub appears to be centered in Eindhoven, Philips also has employees [redacted]

250. Later in 2016, [redacted]

[238] *Id.*

[239] *Id.*

[240] [redacted]

[241] [redacted]

[redacted]

251. In December 2018, [redacted]

252. In May 2020, [redacted]

242 [redacted]

243 [redacted]

244 [redacted]

245 [redacted]

246 [redacted]

247 [redacted]

[redacted]

253. On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the FDCA, 21 U.S.C. § 360h(b) (the "518(b) Notice").[253] The 518(b) Notice stated that the FDA's "Center for Devices and Radiological Health (CDRH) is proposing that an order should be issued pursuant to section 518(b)" of the FDCA "to require Philips to submit a plan for the repair, replacement, and/or refund of the purchase price of devices subject to the recall that were manufactured after November 2015, sufficient to assure that the unreasonable risk of substantial

[249] [redacted]

[250] [redacted].

[251] [redacted]

[252] [redacted]

[253] 518(b) Notice (Exhibit "72" hereto).

harm to the public health presented by those devices will be eliminated."[254] This notice was directed to Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, for Philips Respironics, Inc.

254. The 518(b) Notice stated that "there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health" and "that there are reasonable grounds to believe that the recalled devices that Philips manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture."[255]

255. The FDA concluded that "patients and providers cannot readily mitigate the unreasonable risk associated with the recalled devices."[256]

256. The FDA also concluded that "[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR foam."[257]

1. In 2015, Philips Communicated With Its Foam Suppliers About The Problem Of PE-PUR Foam Degradation.

257. The PE-PUR foam that Philips used in its Recalled Devices was manufactured by William T. Burnett & Co. ("Burnett"), a bulk foam manufacturer. Burnett produces foam in sheets that are between approximately four feet to more than six feet wide and may be as long as one hundred or two hundred feet.

---

[254] *Id.* at 1.

[255] *Id.* at 2.

[256] *Id.*

[257] *Id.* at 6.

258. Burnett sells its bulk foam to intermediaries, including PolyTech and The SoundCoat Company ("SoundCoat"). PolyTech and SoundCoat then sell the foam to Philips, either directly or through another intermediary, such as Paramount Die Corporation, which may modify the foam.

259. According to the FDA, "email correspondence between [Philips] and its raw foam supplier [PolyTech] beginning 10/30/2015 and forward, document that [Philips] was made aware of polyester polyurethane [PE-PUR] foam degradation issues in/around October 2015, which was later confirmed by [Philips'] foam supplier on 08/05/2016, via email."[258]

260. On August 5, 2016, Bob Marsh, a PolyTech employee, wrote to Lee Lawler,[259] an employee of Burnett, referencing a concern expressed by one of its customers, Philips, in the Fall of 2015 regarding foam degradation in its medical devices.[260] Mr. Marsh stated: "They [Philips] are asking again, and wondered if we could give them any estimate on lifespan of the foam when exposed to 40 C and high humidity."[261] Mr. Lawler responded that, under those conditions, he "would not be surprised if ester foam . . . would exhibit signs of hydrolysis in as short a time as a year."[262] He added: "that is not a good environment for polyester foam. Polyether foam could last years in that environment."[263] Presumably referring to Philips, Mr. Marsh responded that he would

[258] 483 Report (Exhibit "5" hereto), at 18.

[259] The Affidavit of Lee Lawler, Technical and R&D Manager at Burnett ("Lawler Aff."), is filed in MDL No. 3014, Case 2:21-mc-01230-JFC, at ECF 589-7, and attached hereto, without exhibits, as Exhibit "94."

[260] *See* Email exchange between Bob Marsh at PolyTech and Lee Lawler at Burnett (Lawler Aff. Exh. E) (attached hereto as Exhibit "95"), at WTB 000056.

[261] *Id.*

[262] *Id.*

[263] *Id.*

"let them know they'd be better off with the ether."[264] [redacted]

261. Indeed, [redacted]

262. Knowing about these issues with the PE-PUR foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, "this testing spoke only to the limited finding that in the case of the [redacted] foam samples 'returned from service in a Pacific rim location,' spectroscopy results were 'consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material.'"[267] Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.[268]

263. According to the FDA, "no further investigation, health hazard evaluation, risk analysis, or design review was performed or documented by Philips at that time . . . and no preventative maintenance procedures were implemented," other than a limited "preventative maintenance procedure" instituted by a Philips "entity owned by the parent company of Philips Respironics … to replace the air intake assembly of Trilogy ventilator products, due to complaints

[264] *Id.*

[265] [redacted]

[266] [redacted]

[267] 518(b) Notice (Exhibit "72" hereto), at 7.

[268] *Id.*

that had been received regarding degradation of the PE-PUR foam contained in the products."[269] And even then, "Philips did not verify the effectiveness of this measure."[270]

264. As Philips continued to ask its supplier about the properties of the PE-PUR foam and encountered more warning signs, it continued to put that foam in medical devices that millions of its customers were breathing through daily.

265. Testing conducted for Philips in 2016 confirmed that Mr. Lawler from Burnett was correct. According to the FDA, this testing "determined that the PE-PUR foam was susceptible to degradation, resulting in the conclusion at that time that 'polyester urethanes show bad resistance against high humidity in combination with high temperature.'"[271] Additional testing "determined that, compared to PE-PUR foam, another type of foam, polyether urethane, 'show[s] a far better resistance against high humidity at high temperature.'"[272]

266. The 483 Report identified "at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices."[273] It listed the specific analyses and tests, including one which concluded that "contrary to polyester urethane foams, [redacted] foams shows a far better resistance against high humidity at high temperature."[274]

---

[269] *Id.* at 6-7.

[270] *Id.* at 8.

[271] *Id.* at 7-8.

[272] *Id.* at 8.

[273] 483 Report (Exhibit "5" hereto), at 3.

[274] *Id.* at 4.

267. Philips received at least 110 complaints confirmed to be related to foam degradation between 2014 and 2017.[275] Approximately 80 of these complaints concerned CPAP and BiPAP devices.[276]

268. Nonetheless, Philips continued manufacturing and selling the now Recalled Devices containing PE-PUR foam and failed to warn prescribing physicians, durable medical equipment companies and the patient consumers of this problem.

2. Philips Opened An Internal Investigation Into Foam Degradation In Mid-2018 That Confirmed PE-PUR Foam Is Prone To Degradation.

269. In April 2018, Philips opened a precursor to a formal CAPA, referred to by Philips as a CAPA INV 0988, "to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken."[277] Philips reported that "[u]nits were returned from the field where the Trilogy Removable Air Path Foam [redacted] and the foam in the Inlet Air Path Assembly [redacted] was degrading, and getting into the motor/air path, causing at least 1 Trilogy unit to fail."[278]

270. On April 20, 2018, Vincent Testa, a Project Mechanical Engineer at Philips RS, emailed Bonnie Peterson, a Project Manager at PolyTech. Mr. Testa stated, "We use the PAFS

[275] 518(b) Notice (Exhibit "72" hereto), at 7.

[276] *Id.* at 8.

[277] *Id.* [redacted]

[278] 483 Report (Exhibit "5" hereto), at 14.

foam in the air path of our Trilogy family of ventilators as a means for noise reduction . . . ."[279] PAFS foam is PolyTech's open cell, flexible acoustical grade PE-PUR foam.[280] Mr. Testa at Philips continued: "Recently weve [*sic*] received a few complaints from our customers that the foam is disintegrating . . . . The material sheds and is pulled into the ventilator air path. As you can imagine, this is not a good situation for our users."[281] Mr. Testa asked, "what could cause this material to break down."[282]

271. On April 23, 2018, Mr. Marsh from PolyTech forwarded Philips' April 20, 2018 email to Mr. Lawler from Burnett, reporting that "[t]he customer [Philips] is finding degradation of the ester foam and the urethane film in their device, such that particles are breaking off and flowing in the airstream."[283]

272. On May 2, 2018, Mr. Marsh added in an email to Mr. Lawler that "Philips gave us another bit of information. They tested ether vs ester in high heat and humidity and found ether to be the better performer. It validated what we (you) had conveyed."[284] Mr. Marsh asked whether exposure to oxygen, higher temperature, and higher humidity could accelerate deterioration of PE-PUR foam.[285]

---

[279] *See* Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H) (attached hereto as Exhibit "98"), at WTB 000070.

[280] *See* PolyTech website, https://www.polytechinc.com/products/acoustic-foamhttps://www.polytechinc.com/products/acoustic-foam (last accessed Oct. 3, 2022).

[281] *See* Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H) (Exhibit "98" hereto), at WTB 000070.

[282] *Id.*

[283] *See* Email from Bob Marsh to Lee Lawler dated 4/23/2018 (Lawler Aff. Exh. H) (Exhibit "98" hereto), at WTB 000069-70.

[284] *See* Email from Bob Marsh to Lee Lawler dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit "98" hereto), at WTB 000069.

[285] *Id.*

273. Mr. Lawler responded that he did "not believe that exposure to oxygen will cause any significant damage to polyurethane foam unless elevated temperature and/or humidity is also present."[286]

274. On May 3, 2018, Mr. Testa from Philips admitted in a follow-up email to Mr. Marsh from PolyTech, that:

> We [Philips] are evaluating our options regarding the foam. We could switch to the PAF [ether-based foam], or we could indicate a preventative maintenance cycle in which they would replace the PAFS [ester-based] foam pieces. . . . The environmental conditions for our device are a maximum of 40C and 95% R.H. Note the difference in temperature.[287]

275. Mr. Testa at Philips asked Mr. Marsh from PolyTech the following:

> 1. Please ask your foam supplier to calculate the service life based on this higher temperature (40C vs. 27C).
>
> > a. It would also be useful if they could provide a graph depicting failure over time. For example, if tensile strength reduced over time, they would plot strength vs. time.
>
> 2. At the end of the service life, what is the failure mode of this material?[288]

276. Mr. Marsh again forwarded these questions to Mr. Lawler at Burnett, who responded:

> I am unable to answer Question Number 1. We would not recommend using **polyester** foam in such an environment and have no direct data to use to calculate the rate of hydrolysis. **Polyether** foam lifetime would not be expected to reduce significantly at the stated conditions. Use with pure oxygen could shorten the lifetime some by promoting more rapid oxidation. I do not know the extent of the reduction, but do not expect it to be overly significant.

---

[286] *See* Email from Lee Lawler to Bob Marsh dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit "98" hereto), at WTB 000069.

[287] *See* Email from Vincent Testa to Bob Marsh dated 5/3/2018 (Lawler Aff. Exh. H) (Exhibit "98" hereto), at WTB 000068-69).

[288] *Id*.

> Polyester foam will lose tensile strength and overall integrity as it hydrolyzes. It will eventually decompose to a sticky powder. That will happen very rapidly at 40C, 95% R.H.[289]

277. Mr. Lawler from Burnett added: "Is it one of our data sheets that states foam lifetime being 10 years at 95% R.H? I do not think I have seen a sheet with that statement."[290] Mr. Marsh at PolyTech responded that he would pass along the information to Philips and that "[w]e have no idea where that statement came from. It has been on our data sheets for probably 20 years. We are removing it."[291]

278. On May 23, 2018, Mr. Marsh from PolyTech forwarded to Mr. Lawler from Burnett another question from Mr. Testa at Philips, about the degradation of the foam it was using in its Recalled Devices.[292] Mr. Testa explained that Philips had "sent samples to a local lab for analysis."[293] The local lab concluded that the degradation was a result of cleavage of the bonds in the base polymer, and Mr. Testa stated that "[f]urther investigation concluded that prolonged exposure to high humidity causes the foam to degrade."[294] Mr. Testa noted that "[a]s the foam

---

[289] *See* Email from Lee Lawler to Bob Marsh dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit "98" hereto), at WTB 000067-68 (emphasis in original).

[290] *Id.* at WTB 000068.

[291] *See* Email from Bob Marsh at PolyTech to Lee Lawler at Burnett dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit "98" hereto), at WTB 000067. Notably, PolyTech still advertises on its website that PE-PUR foam is resistant to heat and humidity. *See* PolyTech "Acoustic Foam for Sound Adsorption" webpage, https://www.polytechinc.com/products/polymer-acoustic-foam (last accessed Oct. 7, 2022) ("Ester foams have superior physical properties and offer excellent resistance to heat, moisture, and chemicals.") (attached hereto as Exhibit "99").

[292] *See* Email from Bob Marsh to Lee Lawler dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit "98" hereto), at WTB 000066-67.

[293] *Id.* at WTB 000066.

[294] *Id.* at WTB 000067.

degrades it breaks down into small particulate" and asked whether the foam "maintain[s] its UL 94 Flame Resistance rating if it is broken down into particulate?"[295]

279. Mr. Lawler replied: "I am sure the degraded foam will not perform well in UL94 testing, though I cannot imagine how one would actually perform the test on such degraded material."[296]

280. On June 7, 2018, Mr. Testa at Philips again emailed Mr. Marsh at PolyTech:

> As we continue our investigation of the deterioration of the PAFS foam, a few questions has [*sic*] been posed regarding the material. Can you please reach out to your foam supplier regarding the following.
>
> 1. What is the actual composition of the polyurethane-ester foam PAFS-038? (CAS #s/percentages/weight percent/reactive groups etc. any chemistry is very appreciated)
>
> 2. What kind of diisocynate is used in the polyurethane foam synthesis process and how much?
>
> 3. Is diethylene glycol or another polyol utilized in the foam synthesis process?
>
> 4. Have you tested to see if all diisocyanate groups are reacted in your foam or are there unreacted groups even after manufacturing?[297]

281. Mr. Marsh (PolyTech) forwarded the questions to Mr. Lawler (Burnett), who asked why Mr. Testa (Philips) needed this information. Mr. Marsh did not provide a definitive answer but said, "What Vince [Testa] told us is that they are investigating alternatives to polyurethane

---

[295] *Id.*

[296] *See* Email from Lee Lawler to Bob Marsh dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit "98" hereto), at WTB 000066.

[297] *See* Email from Vincent Testa to Bob Marsh dated 6/7/2018 (Lawler Aff. Exh. I) (attached hereto as Exhibit "100"), at WTB 000076-77.

foam (ester and ether)."[298] Mr. Lawler ultimately did not answer Mr. Testa's questions because they touched on Burnett's confidential, proprietary information.

282. On June 20, 2018, Philips closed CAPA INV 0988.[299] According to the FDA, Philips implemented "a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure."[300] Yet, "after CAPA INV 0988, Philips modified its CAPA procedures to include 'requirements to help ensure that CAPAs are fully complete [and] appropriately scoped,' and that 'processing the issue [that was the subject of CAPA INV 0988] through the current CAPA program would have result[ed] in an appropriate horizontal assessment.'"[301]

283. The FDA pointed out that Philips' informal CAPA INV[302] related to these Trilogy devices did "not include, investigate, or examine all of [Philips'] CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane [PE-PUR] foam, which is susceptible to degradation."[303] But Philips had acknowledged to the FDA that it had "received approximately eighty complaints related to foam degradation, **on non-Trilogy ventilator devices**, from 2014 to 2017."[304]

---

[298] *See* Email from Bob Marsh to Lee Lawler dated 6/14/2018 (Lawler Aff. Exh. I) (Exhibit "100" hereto), at WTB 000075.

[299] 483 Report (Exhibit "5" hereto), at 15.

[300] 518(b) Notice (Exhibit "72" hereto), at 8.

[301] *Id.*

[302] The 483 Report explained that Philips' practice at the time was to first open CAPA requests—called "CAPA INVs"—as a precursor to a formal CAPA, but this could only occur if approved by a "CAPA Review Board" or delegate. *See* 483 Report (Exhibit "5" hereto), at 14-15.

[303] *Id.* at 15.

[304] *Id.* at 16 (emphasis added).

284. The FDA concluded that Philips had not "adequately established" a process for initiating CAPA procedures.[305] Specifically, the FDA faulted Philips for not initiating a "formal" CAPA after receiving "various complaints alleging foam degradation in Trilogy ventilator devices" and then closing its informal investigation just two months later without "verify[ing] the effectiveness" of the limited "preventative maintenance procedure for Trilogy devices."[306]

285. Philips continued to receive more information suggesting that the PE-PUR foam was prone to degradation. According to the FDA, "[a] follow-up email amongst [Philips'] personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints . . . ."[307]

286. Further, "[o]n December 12, 2018, several months after CAPA INV 0988 was closed, a report from additional testing conducted for Philips found that '[p]olyester polyurethane foam showed clear disintegration after 2 weeks."[308]

287. Nonetheless, Philips continued manufacturing and selling the Recalled Devices containing PE-PUR foam.

288. Philips failed to apprise the FDA of the facts and problems it learned from its foam suppliers about premature foam degradation risks.

289. Philips failed to apprise the FDA of consumer, medical provider and durable medical equipment company reports of the presence of foam particles and other device failures.

---

[305] *Id.* at 14.

[306] 518(b) Notice (Exhibit "72" hereto), at 8.

[307] 483 Report (Exhibit "5" hereto), at 18.

[308] 518(b) Notice (Exhibit "72" hereto), at 8.

3. Philips Finally Opened A Formal CAPA In 2019 – But Did Not Initiate A Recall For Two More Years.

290. In April 2019, Philips received two complaints that "sound abatement foam 'is degrading and entering the air path.'"[309]

291. In response, in June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR foam. But as the FDA explains:

> Even then, that CAPA failed to evaluate all relevant data. Philips' search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MDR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips' analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with CAPA INV 0988.[310]

292. Philips continued to test the PE-PUR foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that "the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern…."[311]

293. Another internal "Biological Risk Assessment" dated December 10, 2020 – and "conducted as a result of field reports/complaints regarding degraded sound abatement foam in

---

[309] *Id.*

[310] *Id.* at 8-9.

[311] 483 Report (Exhibit "5" hereto), at 7 ("Philips Respironics Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam.") (quoting July 2, 2020 Biological Risk Assessment).

various CPAP and ventilator products"[312] – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

> The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples **indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.** Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, **the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.**[313]

294. An additional Philips' Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR foam "presents a significant biological risk to patients," and admitted that "[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure."[314]

295. Ultimately, in CAPA 7211, Philips concluded that "the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity" and reiterated that "the cause of degradation was due to chemical breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions."[315]

296. Based on its investigation, the FDA concluded that Philips' upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything to rectify or mitigate the hazards:

> [F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and

[312] *Id.* at 8-9.

[313] *Id.* at 7-8 (emphasis added).

[314] *Id.* at 8.

[315] 518(b) Notice (Exhibit "72" hereto), at 10.

> Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.
>
> Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020 . . . . Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.[316]

F. PHILIPS CONSISTENTLY MARKETED ITS BREATHING MACHINES AS SAFE AND EFFECTIVE EVEN WHEN IT KNEW OF THE PROBLEMS WITH PE-PUR FOAM DEGRADATION AND ASSOCIATED HEALTH RISKS.

1. Philips Never Hinted at the Dangerous Condition of the Recalled Devices.

297. At no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in its recalled CPAP, BiPAP, and ventilator devices. Instead, Philips held itself out as a trusted brand and "global leader in the sleep and respiratory markets."[317] Its branding promises consumers that they will "[b]reath easier, sleep more naturally."[318] Philips further assures consumers that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind," and that its "quality systems reflect [Philips'] commitment to providing enhanced patient comfort," among other things.[319] And it has long advertised its CPAP and BiPAP Machines as "clinically proven" treatment for sleep disorders.[320]

---

[316] 483 Report (Exhibit "5" hereto), at 24.

[317] *See* Philips Respironics website – About Philips Respironics, http://www.respironics.com/product_libraryhttp://www.respironics.com/product_library (last accessed Oct. 3, 2022) (attached hereto as Exhibit "101").

[318] *Id*.

[319] *See* https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy (last accessed Oct. 3, 2022) (Exhibit "102" hereto).

[320] *Id.*

298. Philips boasts that it has the "most prescribed CPAP systems by U.S. sleep physicians."[321] The CPAP and BiPAP machines routinely cost from seven or eight hundred dollars to thousands of dollars per machine, and the ventilators cost more than several thousands of dollars per machine.

2. Philips Knew Some of its Customers Were Using the SoClean Ozone Cleaning Technology with its Devices and Assented to Such Use.

299. Philips was fully cognizant that many users were utilizing the So-Clean Ozone product in conjunction with its device.

300. For example, on March 6, 2020, in a letter responding to a customer's request for written guidance, Philips Respironics said using SoClean on its DreamStation will not automatically void the warranty, but the company "reserves the right to void a warranty if it is determined that the use of SoClean caused a defect for which a device otherwise under warranty was returned."[322] The company said in a statement to HME News that it "does not formally validate the use of SoClean with the DreamStation, but as of Jan. 6, Philips has not denied a warranty claim associated with the use of SoClean with a DreamStation."[323] Philips told HME News it wrote the letter "to limit confusion and misinformation."[324] The article in HME News further quoted Philips stating that "Philips is in communication with SoClean to further analyze the potential

[321] *Id.*

[322] *Business News For Home Medical Equipment Providers* (March 6, 2020), at https://www.hmenews.com/article/cpap-manufacturers-address-certain-cleaning-devices (last accessed Oct. 3, 2022) (attached hereto as Exhibit "103").

[323] *Id.*

[324] *Id.*

compatibility of the SoClean with DreamStation therapy devices, and will provide further information as it becomes available," the company told HME News.[325]

301. By virtue of that communication to a trade journal, Philips not only acknowledged its awareness of the use of the product, but also acknowledged it received warranty complaints amongst users of the DreamStation who also used SoClean, and honored the warranties and communicated with SoClean.

302. Additional evidence that Philips was aware that SoClean was selling a product specifically designed to be used in conjunction with the DreamStation is the website of CPAPDIRECT.COM, a major internet provider of CPAP machines and related paraphernalia which advertised an express adapter kit for So Clean and Dream Station products.[326] Similarly numerous other internet and durable medical equipment companies and retail suppliers of Philips CPAP devices also sold SoClean to be used in conjunction with the Devices, and Philips expressly and impliedly was aware of this combined use.

303. Given that Philips was on notice since at least 2008 of a foam degradation concern, and was also aware of the combined use of its Devices with SoClean, to the extent there is any validity to Philips recent claims attributing foam degradation to SoClean ozone treatment, Philips should have and could have made the same attributions and affirmatively stepped up to expressly warn medical providers, Durable Medical Equipment companies and patients against the combined use of the products in allegedly contributing to premature foam degradation.

---

[325] *Id.*

[326] *See* CPAP Direct Products Page – SoClean Respironics System One & DreamStation Adapter, https://www.cpapdirect.com/cleaning/soclean-respironics-system-one-and-dreamstation-adapter (last accessed Oct. 3, 2022) (attached hereto as Exhibit "104").

304. Instead, recognizing that SoClean consumers seemingly liked having this additional cleaning modality, Philips declined to dissuade patients and customers from the combined use due to a concern that they would lose business to alternative CPAP manufacturers who also tacitly or expressly condoned such joint use.

3. Philips Sold Its Humidifier Accessory Allowing Warm Storage Conditions and Contributing to Humidity of the Foam.

305. Philips sold humidifiers to accompany its CPAP devices,[327] especially the DreamStation, stating in the humidifier's User Manual under the heading "Intended Use": "The DreamStation Heated Humidifier is an accessory for the Philips Respironics DreamStation therapy devices to provide moisture to the patient circuit."[328]

306. The humidifier manual quoted above had, under the heading "DreamStation Heated Humidifier Specifications" had environmental specifications that included an "Operating Temperature: 5° to 35° C (41° to 95° F")" as well as "Storage Temperature: -20° to 60° C (-4° to 140° F)" and "Relative Humidity (operating & storage): 15 to 95% (non-condensing)."[329]

307. Philips provided the humidifier option explaining in the DreamStation User Manual that "[y]ou can use the heated humidifier and the heated tube with your device. They are available from your home care provider. A humidifier may reduce nasal dryness and irritation by adding moisture to the airflow."[330]

---

[327] Philips' humidifiers are not compatible with CPAP devices manufactured by other companies like ResMed.

[328] *See* DreamStation Humidifier User Manual, https://www.documents.philips.com/doclib/enc/11410694/DreamStation_Humidifier_User_Manual.pdf, at 1 (last accessed Oct. 3, 2022) (attached hereto as Exhibit "105").

[329] *Id.* at 12.

[330] *See, e.g.*, DreamStation User Manual (Exhibit "47" hereto), at 22.

308. Philips not only knew but recommended the use of the humidifier, and also advised that the device could be stored in a room as warm as 140° F despite their knowledge that warm, hot and humid conditions contributed to rapid degradation of its sound insulating foam.

309. The vast majority of DreamStation patients use the Philips humidifier with their devices.

G. PHILIPS FINALLY RECALLED ITS DEFECTIVE DEVICES CONTAINING HAZARDOUS PE-PUR FOAM, BUT ONLY AFTER LAUNCHING ITS NEWEST DEVICE WITHOUT PE-PUR FOAM.

1. Prior to the Recall, In April And May 2021, Philips Launched The DreamStation 2 (Which Does Not Contain PE-PUR Foam).

310. Two months prior to the Recall, Philips announced on April 13, 2021, that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family. The DreamStation 2 does not contain PE-PUR foam.

311. Less than two weeks after its launch of the DreamStation 2, on April 26, 2021, Philips announced that its previous generation of DreamStation products and other Recalled Devices posed serious health risks to users. In the same release, Philips tried to convince consumers to purchase and use its new DreamStation 2 device:

> Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone,* and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the

> estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.[331]

312. Even when making this announcement, Royal Philips downplayed the significance of the problem claiming "the occurrence rate is very, very low."[332] At the same time, Royal Philips assured its shareholders that any adverse impact on sales due to the safety risks posed by the Recalled Devices was minimized by introduction of the DreamStation 2: "The good thing is, is that we have launched DreamStations 2."[333]

2. Testing Continued To Confirm The Recalled Devices Were Defective and the FDA Received Additional MDRs.

313. Even as it launched the DreamStation 2 device and announced publicly that its previous generation DreamStation products posed serious health risks to users, Philips continued to conduct tests that confirmed some of its breathing products were defective.

314. For example, on May 17, 2021, Ken Cole from RJ Lee, an industrial forensics analytical laboratory and scientific consulting firm, produced a presentation analyzing the foam in Philips' Trilogy EVO devices. The presentation states that the investigation was "prompted by staff observation of color variance across both current production and previous builds."[334]

315. The analysis involved six samples of foam, two from units built in 2018 and four taken from Philips' current production stock in May 2021.[335] Some of the samples from 2021

---

[331] *See* Royal Philips announces its 2021 First-Quarter Results (Apr. 26, 2021), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html (last accessed Oct. 9, 2022) (attached hereto as Exhibit "106").

[332] Transcript of Koninklijke Philips NV Earnings Call for First Quarter 2021 Results (April 26, 2021), Fair Disclosure Wire (attached hereto as Exhibit "107").

[333] *Id*.

[334] *See* RJ Lee Analysis Review of Trilogy EVO Foam (Lawler Aff. Exh. A) (WTB000001-14) (attached as Exhibit "108" hereto), at WTB000003.

[335] *Id.* at WTB 000006.

showed "differing cell structure" which is an "[i]ndication of poor process control."[336] The 2021 foam had "significant contaminants."[337] The foam was supposed to be ether-based,[338] but testing revealed indications that some of the foam was actually ester-based.[339]

316. In addition, MDRs associated with the PE-PUR foam breakdown increased significantly.[340] From 2011 to April 2021 when Philips first notified the FDA of their intention to conduct a field action due to concerns pertaining to foam degradation (breakdown) in certain ventilators, BiPAP machines, and CPAP machines, Philips submitted only 30 MDRs that they identified as associated with the PE-PUR foam breakdown and there were no reports of patient injury or death among those 30 MDRs.[341] Eight of those reports were from the United States.

317. After Philips notified the FDA of its intention to conduct a field action in April 2021 through July 31, 2022, the amount of MDRs the FDA received increased significantly as did

[336] *Id.* at WTB 000008.

[337] *Id.* at WTB 000009; *see also* WTB 000010 ("Indication of poor process control and/or contamination.").

[338] *Id.* at WTB 000002.

[339] *Id.* at WTB 000013.

[340] As stated above, manufacturers, such as Philips, are required to submit medical device reports (MDRs) when information reasonably suggests that their device may have caused or contributed to a death or serious injury, or has malfunctioned, and that device or a similar device they manufacture would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Health professionals, consumers, and patients may voluntarily submit reports of device adverse events and malfunctions to the FDA. *See, e.g.*, 21 C.F.R. § 803.20.

[341] The FDA's latest information about medical device reports (MDRs) associated with the Recalled Devices on August 16, 2022 is available here: https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due?utm_medium=email&utm_source=govdelivery#mdr (last accessed Oct. 3, 2022) ("FDA MDR Update").

the "reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown."[342] Specifically, the FDA reported:

- From April 2021 through April 30, 2022, the FDA received more than 21,000 MDRs, including 124 reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown.

- From May 1, 2022, through July 31, 2022, the FDA received more than 48,000 MDRs, including 44 reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown.

318. The FDA continued: "A wide range of injuries have been reported in these MDRs, including cancer, pneumonia, asthma, other respiratory problems, infection, headache, cough, dyspnea (difficulty breathing), dizziness, nodules, and chest pain."[343]

3. Finally, In June 2021, Philips Recalled Its Defective Devices.

319. Finally, on June 14, 2021, Royal Philips issued a press release announcing a recall notice directed to its customers in the United States, and a field safety notice for the rest of the world, stating:

> To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone, and high heat and high humidity environments may also contribute to foam degradation.

[342] *Id*. (stating "The MDRs received included both mandatory reports from Philips and voluntary reports from health professionals, consumers, and patients.").

[343] *Id*.

> Therefore, Philips has decided to voluntarily issue a recall notification to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.[344]

320. Philips stated that "[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family."[345] Philips elaborated:

> Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification advises patients and customers to take the following actions:
>
> - For patients using affected BiLevel PAP and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.
>
> - For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.
>
> **Possible health risks**
>
> The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity,

[344] Royal Philips Press Release, Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices (June 14, 2021) (Exhibit "34" hereto) (asterisks and footnotes omitted).

[345] *Id.*

> nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions.[346]

321. Corroborating the dangerous nature of the Recalled Devices, on July 22, 2021, the FDA upgraded Philips' recall of the Recalled Devices to its most serious classification, Class I, which according to the FDA means: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."[347]

322. Philips' Recall announcement instructed users to not use the Recalled Devices because of the health risks. This confirmed the true nature of the recalled products, which at all times were adulterated and worthless.

323. Philips took similar action with respect to its defective CPAP, BiPAP, and ventilator devices across the globe.

324. Shortly after Philips' recall announcement, Philips' main competitor, ResMed, issued a message regarding the recall, stating that "ResMed devices are not subject to this recall and are safe for patients to use. ResMed devices use a different material for sound reduction than the material used by the other manufacturer."[348]

---

[346] *Id.* (asterisks and footnotes omitted).

[347] *See* FDA – Recalls Background and Definitions, https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions (last accessed Oct. 3, 2022) (attached hereto as Exhibit "109").

[348] *See* ResMed webpage, Information regarding a separate manufacturer's product recall (June 2021), archived at: https://web.archive.org/web/20210617041516mp_/https://www.resmed.com/en-us/other-manufacturer-recall-2021/ (last accessed Oct. 7, 2022) (attached hereto as Exhibit "110").

325. ResMed devices and ventilators use polyether polyurethane or silicone-based foam, not PE-PUR foam, for sound abatement purposes.[349]

H. THE MEASURES TAKEN BY PHILIPS, AND BY ROYAL PHILIPS IN PARTICULAR, TO RECALL AND REPLACE THE DEFECTIVE DEVICES HAVE BEEN INADEQUATE AND INEFFECTIVE.

326. From the outset, Royal Philips has directly overseen and managed the Recall announced on June 14, 2021.

327. Royal Philips tasked a member of its Executive Committee, Roy Jakobs, with leading the company's repair and remediation program.[350] Mr. Jakobs is in charge of Philips' Connected Care businesses that include Philips RS.[351] Royal Philips claims that "[s]ince taking on

---

[349] *See* ResMed "Other Manufacturer Recall 2021" webpage, An update from ResMed's CEO (Dec. 6, 2021), https://www.resmed.com/en-us/other-manufacturer-recall-2021/ (last accessed Oct. 4, 2022) (Exhibit "51" hereto).

[350] *See* Royal Philips Press Release, Philips announces CEO succession (Aug. 16, 2022) (Exhibit "41" hereto); *see also* video titled "Philips CEO Frans van Houten and Chief Business Leader Connected Care Roy Jakobs talk about the various aspects of the field safety notice," available at: https://www.philips.com/a-w/about/news/archive/standard/news/press/2022/20220628-philips-provides-update-on-philips-respironics-pe-pur-sound-abatement-foam-test-and-research-program.html (last accessed Oct. 3, 2022). With respect to the Recall, Mr. Jakobs has said: "I have a dedicated team of over 1,000 colleagues fully focused on this [the repair and replacement program], supported by many more across the company." *See also* Royal Philips Press Release, Philips provides update on Philips Respironics' PE-PUR sound abatement foam test and research program (June 28, 2022), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/news/philips-provides-update-on-philips-respironics-pe-pur-sound-abatement-foam-test-and-research-program (last accessed Oct. 3, 2022) (attached hereto as Exhibit "111").

[351] *See* Royal Philips First-Quarter Results 2022 (Apr. 25, 2022), available at: https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-first-quarter-results-2022.html (last accessed Oct. 3, 2022) (Exhibit "40" hereto) ("Philips has a strong program management in place led by Roy Jakobs, Chief Business Leader of the Connected Care businesses and member of Philips' Executive Committee, to ensure the Respironics field action is executed with speed and accuracy."); *see also* Royal Philips Investor Call Transcript regarding "Test and research program Respironics PE-PUR sound abatement foam" (June 28, 2022), available at: https://www.philips.com/c-dam/corporate/newscenter/global/standard/resources/healthcare/2022/podcast-healthier-future/Transcript_-_Philips_Test_and_research_program_Respironics_PE-PUR_sound_abatement_foam.pdf (last accessed Oct. 3, 2022) (attached hereto as Exhibit "112").

responsibility for the voluntary recall notification/field safety notice for specific Respironics devices on behalf of Philips, substantial progress has been made under his [Mr. Jakobs'] leadership in the execution of the comprehensive program aimed at delivering a resolution to affected patients as fast as possible in consultation with the relevant competent authorities."[352]

328. In addition to Mr. Jakobs, Royal Philips' Technical Project Manager Jan Bennik "head[s] up the polyester-polyurethane sound abatement foam test and research program."[353] He has spoken publicly on behalf of Philips about the recalled devices.

329. Further, the following additional Royal Philips employees are believed to have knowledge of the Recall of the devices[354]: a) Liz Iversen, Former Chief Quality and Regulatory

[352] *Id.*

[353] Technical Project Manager Jan Bennik speaks about the test and research program, video available at: https://www.philips.com/a-w/about/investor-relations/recall-sleep-and-respiratory/testing.html (last accessed Oct. 3, 2022).

[354] *See* Letter dated September 15, 2022, from all Philips Defendants (attached hereto as Exhibit "113"), at 3-6 (section regarding agreed-upon initial custodians from which to pull responsive discovery).

Officer[355]; b) Jan Kimpen, Chief Medical Officer (Netherlands-based)[356]; and c) Carla Kriwet, Former Chief Business Leader Connected Care (Netherlands-based).[357]

330. Upon information and belief, Philips NA has also been involved with the Recalled Devices and the Recall.[358] For example:

a. Tom Reimann, Head of Quality of Connected Care, likely "has knowledge regarding the manufacture, regulatory evaluation, and quality assurance review of certain devices and the recall of the devices."[359]

b. Thomas Catalano, Director of Product Marketing, is "Lead global product management team in $1 bill sleep business unit."[360] His prior role with Philips was as a Global product Manager, involved with "Development product/service pipeline for next generation of CPAP therapy to treat obstructive apnea."[361]

---

[355] Liz Iversen had "global executive responsibility and accountability" for Royal Philips. On LinkedIn, she described her role with Royal Philips as follows: "Global executive responsibility and accountability for Quality, Regulatory, Clinical, Medical and Compliance to ensure delivery of safe and effective products across the enterprise while executing regulatory and quality strategies in support of business growth." LinkedIn Profile for Liz Iversen, Experience section, https://www.linkedin.com/in/ediversen/ (last accessed Oct. 3, 2022) (attached hereto as Exhibit "114").

[356] As Chief Medical Officer Jan Kimpen "worked collaboratively with business and functional leaders across the organization" including "provid[ing] clinical guidance for the development and market introduction of all new product...[and] advis[ing] Philips' board and management in making decisions on market participation, product development, …and product launches." *See* LinkedIn profile for Jan Kimpen, Experience section (Exhibit "38" hereto).

[357] Ms. Kriwet's LinkedIn Profile states she was the "CEO, Connected Care, Member of the Royal Philips Executive Committee" from 2017-2020. *See* LinkedIn Profile for Carla Kriwet, Experience section, https://www.linkedin.com/in/dr-carla-kriwet/ (last accessed Oct. 3, 2022) (attached hereto as Exhibit "115").

[358] *See* Letter dated September 15, 2022, from all Philips Defendants (Exhibit "113" hereto), at 3-6 (section regarding agreed-upon initial custodians from which to pull responsive discovery).

[359] Philips RS North America LLC's Initial Disclosures, dated May 5, 2022 (attached hereto as Exhibit "116").

[360] *See* LinkedIn Profile for Thomas Catalano, https://www.linkedin.com/in/thomas-catalano-5a66552/ (last accessed Oct. 4, 2022) (attached hereto as Exhibit "117").

[361] *Id.*

c. Francis Kim, EVP Chief Quality & Regulatory Officer[362];

d. Erin Levering, Medical Safety Manager, was responsible for working "with the Post-Market Surveillance team to assess individual complaints for safety concerns and regulatory reporting requirements."[363];

e. Vitor Rocha, Chief Market Leader – "CEO North America, EVP at Philips…responsible for driving growth, expanding market share and advancing Philips' position…"[364];

f. Drilon Saliu, former Connected Care Head of Regulatory Affairs, October 2019 – September 3, 2021[365]; and

g. Jessica Shen, Former Senior Vice President, Global Head of Medical Affairs, Clinical Affairs, HEOR & Regulatory Affairs. April 2015 – August 13, 2021.[366] – "Responsible for pre-market, regulatory approval for commercialization of products and solutions, including the development of key regulatory and clinical strategies to bring new technologies to market with the shortest possible cycle time; and the harmonization of regulatory/clinical processes across all Philips product lines; Work closely with global regulatory officials to further advance Philips' relationship and reputation among these important groups; and continue to build out our core internal competencies and strengthen our regulatory, Medical & clinical team."[367]

331. While the Recall began in the United States, it has been expanded worldwide.[368]

---

[362] *See* LinkedIn Profile for Francis Kim, https://www.linkedin.com/in/francis-k-2b32a111a (last accessed Oct. 7, 2022) (attached hereto as Exhibit "118"); *see also* [redacted]

[363] *See* LinkedIn Profile for Erin Levering, https://www.linkedin.com/in/erin-levering-bs-rn-certified-nurse-practitioner-034920178/?trk=public_post_comment-text (last accessed Oct. 5, 2022) (attached hereto as Exhibit "120").

[364] *See* LinkedIn Profile for Vitor Rocha, https://www.linkedin.com/in/vitor-rocha-98582124/ (last accessed Oct. 4, 2022) (attached hereto as Exhibit "121").

[365] [redacted]

[366] *Id.*

[367] *See* LinkedIn Profile for Jessica Shen, https://www.linkedin.com/in/jessica-shen-md-ms-b386016/ (last accessed Oct. 4, 2022) (attached hereto as Exhibit "122").

[368] *See* Philips website, Urgent Product Defect Correction in Australia (Recall for Product Correction in New Zealand) (Exhibit "9" hereto) (stating that a global recall notification was issued on June 14, 2021 and that recalls specific to Australia and New Zealand were issued on July 2, 2021). Other impacted countries include, but are not limited to, Canada, Israel, and Chile. In

332. Since June 2021, Royal Philips has issued numerous press releases specifically providing information about the worldwide recall.[369]

addition to the litigation initiated against Philips in the United States, "Philips or its affiliates are also defendants in litigation in Australia, Canada, Chile, and Israel, as well as in smaller or individual actions in other countries." Royal Philips First Quarter Results 2022 - Presentation at 37 (Apr. 25, 2022), available for download at https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-first-quarter-results-2022.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "123"). In a video produced by Royal Philips, Chief Business Leader of the Connected Care businesses Roy Jakobs said: "We have more than 5.5 million patients from over 100 countries who need a replacement." *See* Philips video, available at: https://www.philips.com/a-w/about/investor-relations/recall-sleep-and-respiratory/testing.html (last accessed Oct. 3, 2022). For example, there are 350,000 affected Philips CPAP devices and 29,500 affected Philips ventilators in France. ANSM (France) – Public Hearing Comité Scientifique Temporaire (June 8, 2022) video, available at: https://www.youtube.com/watch?v=ctvL0TcmWO8 (last accessed Oct. 3, 2022). In France, the Agence nationale de sécurité du médicament et des produits de santé (ANSM) had public hearings regarding the recall on June 8, 2022. Technical Project Manager Jan Bennik of Royal Philips was among the representatives of Philips who spoke at the hearings. *Id.* CEO van Houten has said that Philips is "[i]n close dialogue with regulators across the world." Philips 2021 Annual Report at 5 (Exhibit "13" hereto). French prosecutors have opened a preliminary investigation into Philips' recall. A spokesperson for the Paris public prosecutor's office said the office had "taken up, as of June 20, 2022, complaints filed on the grounds of aggravated deception, involuntary attacks on physical integrity, endangerment of life of others and administration of harmful substances." Charlotte Van Campenhout, French Prosecutors Probe Philips Respirator Recall, Reuters (Sept. 9, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/french-prosecutors-probe-philips-respirator-recall-france-info-reports-2022-09-08/ (last accessed Oct. 3, 2022) (attached hereto as Exhibit "124").

[369] *See, e.g.*, Royal Philips Press Release, Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices (June 14, 2021) (Exhibit "34" hereto); Philips Press Release, Philips starts repair and replacement program of first-generation DreamStation devices in the US in relation to earlier announced recall notification* (Sept. 1, 2021) (Exhibit "10" hereto); Royal Philips Press Release, Philips provides update on earlier announced voluntary CPAP, BiPAP and Mechanical Ventilator recall notification* (Nov. 14, 2021) (Exhibit "35" hereto); Royal Philips Press Release, Philips provides update on the test and research program in connection with the CPAP, BiPAP and Mechanical Ventilator recall notification* (Dec. 23, 2021), https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20211223-philips-provides-update-on-the-test-and-research-program-in-connection-with-the-cpap-bipap-and-mechanical-ventilator-recall-notification.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "125"); Royal Philips Press Release, Philips Respironics provides update for the US on ongoing CPAP, BiPAP and Mechanical Ventilator field action (Mar. 10, 2022), https://www.philips.com/a-w/about/news/archive/standard/news/press/2022/20220311-philips-respironics-provides-update-

333. Royal Philips also discusses the Recall and the alleged Defect in the products in other communications and press releases such as those about its quarterly results.[370]

334. For example, when the problems with the Recalled Devices were first announced to Philips' shareholders, Royal Philips included in its April 26, 2021 press release regarding First Quarter 2021 results, the following statement from CEO Frans van Houten: "Regretfully, we have identified a quality issue in a component that is used in certain sleep and respiratory care products, and are initiating all precautionary actions to address this issue, for which we have taken a EUR 250 million provision."[371]

---

for-the-us-on-ongoing-cpap-bipap-and-mechanical-ventilator-field-action.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "126"); Royal Philips Press Release, Philips Respironics provides update on filed MDRs in connection with the voluntary recall notification/field safety notice* for specific CPAP, BiPAP and mechanical ventilator devices (May 24, 2022), https://www.philips.com/a-w/about/news/archive/standard/news/press/2022/20220524-philips-respironics-provides-update-on-filed-mdrs-in-connection-with-the-voluntary-recall-notification-field-safety-notice.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "127"); Royal Philips Press Release, Philips provides update on Philips Respironics' PE-PUR sound abatement foam test and research program (June 28, 2022) (Exhibit "111" hereto).

[370] Philips announcement of 2021 First-Quarter Results (Apr. 26, 2021), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html (last accessed Oct. 3, 2022) (Exhibit "106" hereto); Philips announcement of 2021 Second-Quarter Results (July 26, 2021), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-second-quarter-results-2021.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "128"); Philips announcement of 2021 Third-Quarter Results (Oct. 18, 2021), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-third-quarter-results-2021.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "129"); Philips announcement of Fourth Quarter and Annual Results 2021 (Jan. 24, 2022), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-fourth-quarter-results-2021.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "130"); Philips announcement of First-Quarter Results 2022 (Apr. 25, 2022), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-first-quarter-results-2022.html (last accessed Oct. 3, 2022) (Exhibit "40" hereto); Philips announcement of Second-Quarter Results 2022 (July 25, 2022), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-second-quarter-results-2022.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "131").

[371] Philips announces its 2021 First-Quarter Results (Apr. 26, 2021) (Exhibit "106" hereto).

335. In the same press release, Royal Philips said: "Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks."[372]

336. In a June 14, 2021 press release, Royal Philips said: "Philips is initiating a voluntary recall notification to ensure patient safety in consultation with regulatory agencies."[373] Royal Philips CEO van Houten said: "In consultation with the relevant regulatory agencies and in close collaboration with our customers and partners, we are working hard towards a resolution, which includes the deployment of the updated instructions for use and a comprehensive repair and replacement program for the affected devices."[374]

337. This announcement from Royal Philips further stated that "Philips determined based on testing that there are possible risks to users related to this type of foam"; "Philips" decided to issue the recall notification; "Philips has received reports of possible patient impact due to foam degradation"; "Philips is providing the relevant regulatory agencies with required information

[372] *Id.* (footnote omitted).

[373] Royal Philips Press Release, Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices (June 14, 2021) (Exhibit "34" hereto) (asterisk and footnote omitted).

[374] *Id.*

related to the launch and implementation of the projected correction"; and "Philips' recently launched next-generation CPAP platform" is not affected by the foam degradation issues.[375]

338. Mr. van Houten also stated in the Recall announcement on June 14, 2021: "We deeply regret any concern and inconvenience that patients using the affected devices will experience because of the proactive measures we are announcing today to ensure patient safety."[376]

339. Later in 2021, Royal Philips emphasized its involvement in the Recall program in various publications. For example, a presentation on Royal Philips' Fourth Quarter 2021 Results noted: "Regular review cadence with Respironics field action Program Management and Executive Committee."[377] The same presentation said: "Philips' experts as well as certified labs and qualified third-party experts are working closely with the Respironics team."[378] The presentation also indicated an effort to "step-up company-wide program."[379]

340. The 2021 Philips Annual Report shows that in addition to Royal Philips' Management, Royal Philips' Supervisory Board and Royal Philips' Quality and Regulatory Committee were also involved in the Recall. For example, the Royal Philips Supervisory Board reported: "In view of the Philips Respironics voluntary recall notification related to the sound abatement foam in certain sleep and respiratory care products (announced on June 14, 2021), the Supervisory Board regularly discussed this issue and the progress made with respect to the repair

---

[375] *Id.*

[376] *Id.*

[377] Philips Fourth Quarter and Full Year 2021 Results – Presentation at 39 (Jan. 24, 2022), available for download at https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-fourth-quarter-results-2021.html (last accessed Oct. 3, 2022) (attached hereto as Exhibit "132").

[378] *Id.*

[379] *Id.* at 36.

and replacement program with Management."[380] Further, the Royal Philips Quality and Regulatory Committee reported that, at its meetings, it discussed "matters associated with [the recall], such as interactions with regulatory authorities globally, engagement with patients, physicians, customers and durable medical equipment providers, testing, health hazard evaluations, and the status of the repair and remediation plan."[381]

341. At the May 2022 shareholders meeting for Royal Philips, CEO van Houten said: "Our team is laser-focused on resolving the sleep recall."[382] He added, regarding the recall: "We have established a dedicated team of 1,000 colleagues working under the direct supervision of the Executive Committee."[383] He explained: "I can tell you that the Philips Board of Management became aware of the issue and its potential significance in the first quarter of 2021 and took adequate and immediate action. This resulted in the issuance of the field safety notice and start of the remediation actions in the first half of 2021."[384] Van Houten further stated that

> [Royal Philips] took a lot of actions. We have, for example, onboarded new top management in the Sleep & Respiratory Care business. We strengthened quality and regulatory affairs leadership for the group for Connected Care, and for the Sleep & Respiratory care business. And we've also added resources to strengthen specific capabilities, all as the consequence of finding out about this issue.[385]

342. Royal Philips' CEO van Houten made frequent statements about the Recall. For example, in the 2021 Royal Philips Annual Report, Mr. van Houten said: "We identified – through our post-market surveillance processes – that **the sound abatement foam used since 2008 in**

---

[380] Philips 2021 Annual Report (Exhibit "13" hereto), at 95.

[381] *Id.* at 115-16.

[382] Koninklijke Philips NV Annual Shareholders Meeting Transcript (May 10, 2022), Fair Disclosure Wire (attached hereto as Exhibit "133"), at 2.

[383] *Id.*

[384] *Id.*

[385] *Id.* at 8.

certain of our sleep and respiratory care products may degrade under certain circumstances. Subsequently, we issued a voluntary recall notification for affected devices to address potential health risks."[386] In July 2021, he said: "We have mobilized the necessary resources across the company to address the component quality issue in certain of our sleep and respiratory care products."[387] In a January 24, 2022 press release, he said, "we remain extremely focused on repairing and replacing the devices related to the Philips Respironics recall notification."[388] And in April 2022, he said, "[w]e have a strong program management in place overseeing every aspect of the remediation."[389]

343. On the same day that the FDA announced that reports of faulty Philips ventilators and sleep apnea machines had risen, Royal Philips announced that CEO van Houten would be stepping down.[390] CEO van Houten's departure announcement followed a May 2022 Royal Philips shareholders meeting where 80% of shareholders voted against giving Mr. van Houten a bonus. Shareholders were "unhappy about delivery problems and issues with the company's widely used sleep apnea machines."[391]

---

[386] Philips 2021 Annual Report (Exhibit "13" hereto), at 5 (emphasis added).

[387] Philips Second-Quarter Results 2021 (July 26, 2021) (Exhibit "128" hereto).

[388] Philips Fourth Quarter and Annual Results 2021 (Jan. 24, 2022) (Exhibit "130" hereto).

[389] Philips First Quarter Results 2022 (Apr. 25, 2022) (Exhibit "40" hereto).

[390] Toby Sterling and Bart H. Meijer, FDA says faulty Philips device reports accelerating as CEO departs, Reuters, Aug. 17, 2022, https://www.reuters.com/business/healthcare-pharmaceuticals/fda-says-faulty-philips-device-reports-accelerating-ceo-departs-2022-08-17/ (last accessed Oct. 3, 2022) (attached hereto as Exhibit "134").

[391] Roy Jakobs to take over the helm at Philips as Frans van Houten steps down, DutchNews.nl (Aug. 16, 2022), https://www.dutchnews.nl/news/2022/08/roy-jakobs-to-take-over-the-helm-at-philips-as-frans-van-houten-steps-down/ (last accessed Oct. 3, 2022) (attached hereto as Exhibit "135").

344. Royal Philips' public statements demonstrate that it has been involved with U.S. regulatory authorities since the announcement of the Recall. In press releases and other statements, Royal Philips has discussed working with the FDA. For example, in a September 1, 2021 press release, Royal Philips said: "Philips received authorization from the US Food and Drug Administration (FDA) for the rework of the affected first-generation DreamStation devices, which consists of replacement of the PE-PUR sound abatement foam with a new material. Philips anticipates rework to commence in the course of September 2021. In addition to the rework, the company has already started replacing certain affected first-generation DreamStation CPAP devices in the US with DreamStation 2 CPAP devices. Philips remains in dialogue with the FDA with respect to other aspects of the recall notification and mitigation plan in the US."[392]

345. Royal Philips issued the following statement in a November 14, 2021 press release: "'In connection with the voluntary recall notification in June of this year, the FDA has recently conducted an inspection of a Philips Respironics manufacturing facility in the US,' said Frans van Houten, CEO of Royal Philips. 'We will work closely with the FDA to clarify and follow up on the inspectional findings and its recent requests related to comprehensive testing.'"[393]

346. Royal Philips has also stated that it is involved in discussions with the Department of Justice relating to a Proposed Consent Decree. In its press release on Second Quarter 2022 results, Royal Philips said, "the US Department of Justice, acting on behalf of the FDA, recently

[392] Philips Press Release, Philips starts repair and/or replacement program of first-generation DreamStation devices in the US and other markets (Sept. 1, 2021) (Exhibit "10" hereto) (footnote omitted).

[393] Royal Philips Press Release, Philips provides update on earlier announced voluntary CPAP, BiPAP and Mechanical Ventilator recall notification* (Nov. 14, 2021) (Exhibit "35" hereto).

began discussions with Philips regarding the terms of a proposed consent decree to resolve the identified issues [in inspection of U.S. facilities]."[394]

347. Unfortunately, Philips' "recall" was a recall in name only. It did not effectively provide patients with notice of the risks of the Recalled Devices, nor did it provide them with new Philips CPAP, BiPAP, or ventilator devices.

1. Many Patients, Providers, And Others Were Not Notified About The Recall.

348. On March 10, 2022, the FDA issued a Notification Order under § 518(a) of the FDCA.[395] The Notification Order stated that the "FDA has received a number of calls from patients and consumers who contacted FDA to report problems and/or concerns regarding the Recalled Products, but were unaware of the recall and had not been informed of the health risks presented by the Recalled Devices."[396]

349. The FDA estimated that, after nine months of the Recall, only "approximately 50% of patients and consumers who have purchased or received the Recalled Products (excluding ventilators) within the last five years (the service life of the devices) have registered with Philips to obtain a replacement device."[397] But it was "unclear whether the remaining patients and consumers have not registered because they are unaware of the need to register, or because they do not want or need a replacement device from Philips."[398]

---

[394] Philips Second-Quarter Results 2022 (July 25, 2022) (Exhibit "131" hereto).

[395] *See* 518(a) Notification Order, available at: https://www.fda.gov/media/156811/download (last accessed Oct. 3, 2022) (attached hereto as Exhibit "136").

[396] *Id.* at 2.

[397] *Id.*

[398] *Id.*

350. The FDA surveyed 182 consignees to determine whether they had been notified of the Recall and found 28 "who had reported to FDA that they were not aware of the recall."[399] The FDA reported its results to Philips on September 8, 2021, and October 29, 2021, but Philips did not promptly respond. Almost a month later, on November 22, 2021, Philips stated that it had notified 23 of the 28 consignees of the Recall, but Philips did not "indicate whether the consignees identified by FDA had been sent notification before, or only after, they had been identified by FDA as being unaware of the recall."[400] Moreover, Philips' evidence of notification consisted of delivery confirmation receipts, reflecting that written correspondence was delivered to the consignees. As the FDA explained, "[t]ypically, firms demonstrate the effectiveness of its recall communications through evidence more meaningful than a delivery confirmation receipt, such as a returned response form or a documented telephone conversation."[401]

351. Throughout the Recall, the FDA "on multiple occasions has informed Philips that FDA was concerned that Philips' efforts to notify patients and consumers, healthcare providers, and consignees regarding the recall have been insufficient," and has expressed concern that "it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products."[402]

352. Noting "Philips' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products," the FDA issued an order under Section 518(a) of the FDCA ordering

[399] *Id.*

[400] *Id.*

[401] *Id.* at 3.

[402] *Id.*

Philips to give adequate notice.[403] Specifically, the FDA ordered Philips to "notify all health professionals who prescribe or use the Recalled Products, and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products **within the next 45 days**."[404]

2. Philips' Repair and Replacement Program Has Been Extremely Slow, Inadequate, and Ineffective.

353. Those patients who registered their Recalled Devices with Philips for the Recall did not immediately receive replacement devices and were not told when a replacement device would be provided.

354. As Philips' June 14, 2021 announcement explained:

> **Repair and replacement program**
>
> Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.
>
> As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program, Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.[405]

355. In reality, patients may register their DreamStation Recalled Device with Philips for the Recall, but Philips has not immediately replaced the defective PE-PUR foam in the

---

[403] *Id*. at 4.

[404] *Id.* (emphasis in original).

[405] *See* Food and Drug Administration, Philips Issues a Recall Notification*, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/philips-issues-recall-notification-mitigate-potential-health-risks-related-sound-abatement-foam (last accessed Oct. 3, 2022).

DreamStation Recalled Devices. Rather, patients have had to wait, sometimes for many months, for Philips to repair or replace their devices, and many patients are still waiting for a replacement device.

356. As of the date of this Complaint—over a year after the Recall was announced—Philips continues to repair or replace defective DreamStation 1 Recalled Devices. In other words, the Recall remains ongoing.

357. The replacement program for the Trilogy devices has been even slower. Philips has only just begun the rework of affected Trilogy 100/200 devices and Philips projects that the process will take approximately 12-14 months to complete.[406]

358. There is no repair or replacement program for any of the other Recalled Devices recalled by Philips.

359. Due to the design of the Recalled Devices, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. Also, the FDA warns:

> Do **not** try to remove the foam from your device. Trying to or successfully removing the foam may damage the device or change how the device works. It may also lead to more foam or chemicals entering the air tubing of the device.[407]

360. As a result, the Recall leaves patients without safe, free options. Instead, patients may simply be or were forced to buy Philips' next-generation product or a competitor's product—at full price, and indeed, thousands of patients, have already done so.

---

[406] *See* Philips "Ventilation News and Updates" webpage, Trilogy Remediation Update for Business Customers (June 1, 2022) (Exhibit "11" hereto).

[407] https://www.fda.gov/medical-devices/safety-communications/faqs-philips-respironics-ventilator-bipap-machine-and-cpap-machine-recalls (emphasis in original) (last accessed Oct. 3, 2022).

361. Thus, Philips intends to, and is, profiting from its "recall" by selling more of its next generation product, the DreamStation 2, whose launch appears intentionally timed to coincide with the "recall."

362. The FDA also believes that the Recall is not proceeding quickly enough. It recently stated:

> Based on the status of Philips' recall as of the date of this letter [May 2, 2022], CDRH believes that, if an order were to be issued to Philips under section 518(b), the plan submitted by Philips in response to that order should provide for significant improvements to Philips' ongoing repair and replacement activities to speed the pace of remediation and address other deficiencies identified by CDRH and communicated to Philips, to the extent such improvements are achievable by Philips.[408]

* * *

363. As stated above, each Philips Defendant acted as part of one joint enterprise in connection with the design, development, testing, marketing, promotion, and sale of the defective and unreasonably dangerous Recalled Devices. Each Philips Defendant is also independently, directly responsible for the design, development, testing, marketing, promotion and sale of the defective and unreasonably dangerous Recalled Devices.

364. Royal Philips has directly been involved with and independently contributed to, for example, the quality, regulatory, and medical compliance functions for Philips; the Recall both globally and in the United States (which it effectively controlled, managed and coordinated); a research program into the hazards posed by the PE-PUR foam; and through its Chief Medical Officer provides guidance for the development and market introduction of all new product development and launches. Royal Philips made the decision to purchase Philips RS (then Respironics) for $5.6 billion, made the decision to pursue expansion of the CPAP, BiPAP, and

[408] 518(b) Notice (Exhibit "72" hereto), at 13.

ventilator product lines; uses and adheres to a worldwide mandatory training program, General Business Principles, and the Philips Business System to govern the activities of the other Philips Defendants; owns the intellectual property rights that cover the Recalled Devices and tightly controls and protects all of its intellectual property, including that of its CPAP, BiPAP, and ventilator devices, in its own name and in conjunction with Philips RS; and owns and is listed as the copyright holder for the User Manuals for the Recalled Devices. Until the Recall was announced in June 2021, Royal Philips failed to disclose the existence, scope, and material safety risks of the Defect in the Recalled Devices despite its obligations pursuant to the federal securities laws. And through Philips USA, Royal Philips has controlled and managed Philips RS and Philips NA while distributing profits accrued from the Recalled Devices to shareholders of Royal Philips' stock.

365. Philips NA has also been directly involved with and independently contributed to, for example, the design, development, and sale of the Recalled Devices through employees with responsibility for quality and regulatory functions, including pre- and post-market regulatory compliance, and by participating in multiple HHEs relating to customer complaints of foam degradation. Philips NA also had a leading role in the marketing and new product development as it relates to the Recalled Devices. What's more, [redacted] Until the Recall was announced in June 2021, Philips NA failed to disclose the existence, scope, and material safety risks of the Defect in the Recalled Devices.

366. Philips RS likewise designed, manufactured, promoted, and sold the Recalled Devices. Philips RS further received and managed complaints relating to the Recalled Devices;

tested and failed to test the biocompatibility of PE-PUR foam as an element of medical devices; and ultimately implemented the Recall. Philips RS also jointly coordinated with Royal Philips to protect all of Royal Philips' intellectual property, including that related to its CPAP, BiPAP, and ventilator devices. Until the Recall was announced in June 2021, Philips RS failed to disclose the existence, scope, and material safety risks of the Defect in the Recalled Devices.

I. PLAINTIFFS AND CLASS MEMBERS HAVE SUFFERED PAST AND PRESENT INJURY IN THAT THEY HAVE THE PAST, PRESENT AND ONGOING MEDICAL NEED FOR DIAGNOSTIC TESTING DUE TO THEIR PAST, PRESENT, AND ONGOING INCREASED RISK OF DISEASE CAUSED BY PAST AND PRESENT EXPOSURE TO PHILIPS' FOAM TOXINS, RESULTING IN THE PRESENT AND ONGOING NEED TO INCUR THE COST OF SUCH TESTING

367. Plaintiffs and Class members used the Recalled Devices containing PE-PUR foam, and Philips has admitted that PE-PUR foam releases toxic and carcinogenic Foam Toxins. Plaintiffs and Class members have been significantly exposed to the proven hazardous Foam Toxins released by PE-PUR foam in the Recalled Devices. Plaintiffs and Class members have inhaled and/or ingested these Foam Toxins through their respiratory tract and gut, where they were absorbed into tissue and into Plaintiffs' and Class members' bloodstream. Because of their past significant exposure, Plaintiffs and Class members have been in the past, are presently, and will be in the future at an increased risk of illness, disease, or disease process, including cancer, making it presently medically necessary that they undergo diagnostic testing for the early detection of illness, disease or disease process.

368. It has been widely accepted for decades that certain of the Foam Toxins (specifically formaldehyde, DEG, and DD's precursor and successor compounds) are toxic and/or carcinogenic to humans. For decades, scientific literature and regulatory agencies around the world have made clear that exposure to the Foam Toxins causes various adverse health effects, including

cancers.[409] Moreover, the synergistic effects of having multiple toxic and carcinogenic materials in the body at the same time likely compound the adverse health outcomes.

369. Philips understood, at all relevant times, that a chemical that causes cancer in animal studies must be presumed to present a risk of cancer to humans, except in extraordinarily limited circumstances; specifically, when (1) the precise mechanism of action that causes tumors is known, and (2) it is also known that the mechanism of action is either not operative or cannot occur in humans. That extraordinary circumstance does not exist here.

370. Studies show that the persistent exposure to the Foam Toxins results in their presence, accumulation, toxic invasion, and/or persistence in the human tissues and bloodstream, including the tissues and bloodstream of Plaintiffs and Class members.

371. Moreover, based on available scientific literature, exposure to the Foam Toxins places Plaintiffs and Class members at increased risk of developing a number of serious illnesses and diseases, including but not limited to the following: cancer, including cancer as of the head, neck, kidneys, liver, brain, pancreas, blood-forming tissue, respiratory system, gastrointestinal system, reproductive system, and lymphatic system; respiratory diseases such as asthma, chronic bronchitis, chronic obstructive pulmonary disease, constrictive bronchiolitis or obliterative bronchiolitis, emphysema, interstitial lung disease, pleuritis, pulmonary fibrosis, sarcoidosis; and chronic sinusitis, chronic rhinitis, and other forms of chronic inflammation. The Foam Toxins are cytotoxic and genotoxic; as such, exposure causes widespread damage to DNA as well as the reproductive system, neurological system, and other critical systems.

372. Philips did not seek or obtain permission or consent from Plaintiffs or Class members before engaging in such acts and/or omissions that caused, allowed, and/or otherwise

[409] The health effects of the Foam Toxins are discussed at length above.

resulted in the contamination of Plaintiffs' and Class members' bloodstream and/or bodies with the Foam Toxins.

373. As a proximate result of Philips' tortious conduct, Plaintiffs and Class members have been, are presently, and will be in the future at an increased risk of illness, disease, or disease processes, including cancer, making it presently reasonably medically necessary for them to incur, both now and in the future, the cost of monitoring, diagnostic testing, clinical examinations, and consultations for the early detection of illness, disease, and disease processes arising from their exposure to the Foam Toxins during use of the Recalled Devices.

374. Plaintiffs have a legally protected interest in not being exposed to harmful particles and toxic chemicals-such as the Foam Toxins-that increase the risk of illness, disease, and disease processes. Plaintiffs and Class members also have a legally protected interest in avoiding the past, present and ongoing medical need for expensive medical monitoring, diagnostic testing, clinical examinations, and consultations, and the cost associated with these diagnostic measures.

375. Plaintiffs and Class members have been exposed to proven hazardous substances in the Foam Toxins, resulting the past, present and ongoing increased risk of illness, disease, and disease processes, causing Plaintiffs and Class members a present and ongoing economic injury. This economic injury consists of the need to incur the cost of medically necessary monitoring, diagnostic testing, clinical examinations, and consultations for the early detection of illness, disease, and disease processes, a need caused by Philips' tortious design, manufacture, marketing, sale of, and post-marketing conduct.

376. Plaintiffs and Class members should not have to wait until illness, disease or disease process or other adverse effects from the Foam Toxins manifest or become recognized before receiving appropriate medical care to treat deleterious health conditions.

377. Plaintiffs and Class members should not have to bear the burden of funding and/or performing such medical monitoring or diagnostic testing which will likely cost millions of dollars, when Plaintiffs and Class members did not consent or provide any permission to Philips to put the Foam Toxins and VOCs in their blood and/or bodies (nor were they even aware they were being contaminated with such compounds), and Philips has reaped billions of dollars in profits. This is particularly true where Philips deliberately and knowingly caused Plaintiffs' and Class members' exposure to the Foam Toxins, despite their well-documented health hazards. To be sure, Plaintiffs and Class members were not even aware that they were being contaminated with such compounds as a result of Philips' decade-long concealment of the PE-PUR Foam's deleterious degradants and its abdication of FDA mandated duties to adequately test its medical devices and immediately, accurately, and comprehensively report those results, as well as conduct appropriate post-market investigations concerning adverse events.

378. Medical monitoring is recognized as beneficial for early detection where there is an increased risk of disease from exposure to hazardous substances.[410] The purpose of medical monitoring in the form of diagnostic testing is early identification of latent or unrecognized illness, disease, or disease process so that early treatment can be given to reduce the impacts of the toxic exposure.[411] Medical monitoring is widely accepted as a prudent response to toxic exposure.[412]

---

[410] ATSDR's Final Criteria for Determining the Appropriateness of a Medical Monitoring Program Under CERCLA, 60 F.R. 38841, July 28, 1995.

[411] *Id.*

[412] *See* http://www.c-8medicalmonitoringprogram.com/docs/med_panel_education_doc.pdf (last accessed August 10, 2021); Department of Environmental Health, *Fernald Medical Monitoring Program*, UNIVERSITY OF CINCINNATI COLLEGE OF MEDICINE, https://med.uc.edu/eh/research/projects/fcc/fmmp-history (last accessed August 10, 2021); Environmental Health & Safety, *Pesticide Users Medical Monitoring Program*, UNIVERSITY OF FLORIDA (revised Jan. 21, 2014), http://www.ehs.ufl.edu/programs/ih/pesticide/ (last accessed August 10, 2021); World Trade Center Health Program, *About the Program*, CENTERS FOR

379. Philips' tortious conduct constitutes an invasion of the legally protected interests of Plaintiffs and Class members and has injured Plaintiffs and Class members. Plaintiffs and Class members would not have the increased risk of illness, disease or disease process and consequent ongoing need to incur the cost of medically necessary monitoring, diagnostic testing, clinical examinations, and consultations to identify the presence of illness, disease, or disease processes arising from their exposure to the Foam Toxins, but for the past and ongoing exposure they suffered as a proximate result of the tortious conduct of Philips.

380. Diagnostic and monitoring procedures exist that make possible the early detection of the toxic effects of the Foam Toxins. These monitoring procedures will benefit Plaintiffs and Class members because they will allow for the early detection of latent or unrecognized disease associated with exposure to toxic PE-PUR foam. Catching cancer and other potentially serious and chronic health issues early allows for early and greater treatment options, improves patient prognoses, and generally avoids more invasive, risky, and expensive medical interventions later. Overall outlook depends on early diagnosis; the sooner a person is checked, the better the outcome will be.[413]

381. Such monitoring procedures in the form of periodic consultations, clinical examinations, and diagnostic testing conform to the standard of medical care and are reasonably necessary to ensure that illness and disease processes can be identified early and aggressively treated. Effective medical consultations, clinical examinations and diagnostic tests exist for reliable early detection, and early detection combined with effective treatment will significantly

---

DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/wtc/about.html (last updated Dec. 15, 2017).

[413] https://www.cancer.org/content/dam/CRC/PDF/Public/8671.00.pdf (last accessed August 10, 2021).

decrease the severity of the illness, disease, disease process, or injury. The present value of the costs of such tests is calculable, and Plaintiffs and Class members will prove such costs at trial.

382. Such monitoring procedures include testing and screening necessary to detect the existence of the illnesses, diseases, and disease processes caused by exposure to the Foam Toxins as described herein, including but not limited to blood and laboratory tests; physical examinations; imaging; colonoscopies, endoscopies, and other similar methods for examination; biopsies; pathologic, histologic, and oncologic evaluations; oncologic, histologic, surgical, and other necessary medical consultations; and medical and surgical procedures necessary for diagnosis and treatment.

383. These monitoring procedures are different in type, timing, frequency and/or scope from what would normally be recommended in the absence of exposure to the Foam Toxins. The general unexposed population does not receive these procedures type, timing, frequency and/or scope because, e.g., these tests are designed to detect the specific diseases known to be associated with exposure to the Foam Toxins.

384. Because of their exposure to the Foam Toxins, Plaintiffs and Class members require medically necessary monitoring, diagnostic testing, clinical examinations, and consultations to diagnose the warning signs of the illness, diseases, and/or disease processes resulting from exposure to the Foam Toxins. Early detection of illness, diseases and disease processes caused by exposure to the Foam Toxins allows Plaintiffs and Class members more treatment options, reduces their cost of treatment, and increases their chances of an improved outcome. The progression from subcellular or other latent physiological changes in Plaintiffs and Class members to the outward manifestation of serious disease can be delayed for years. If the illness, disease, or disease process is permitted to develop until it becomes obvious or recognized, Plaintiffs and Class members will

have lost valuable time and as diseases progress, they will likely suffer more severe or long-term adverse health effects and require more costly medical interventions.

385. Plaintiffs' and Class members' present need to incur the cost of medical monitoring, diagnostic testing, clinical examinations, and consultations is reasonably medically necessary as a direct and proximate result of Philips' conduct that caused Plaintiffs' and Class members' exposure to the Foam Toxins, and the increased risk of illness, disease and disease process that have resulted from the exposure.

386. Accordingly, in this Medical Monitoring Class Complaint, Plaintiffs and Class members seek as damages the costs of such medical monitoring for the early detection of illness, disease, and disease processes beneficial to Plaintiffs and Class members, or in the alternative, the award of the reasonable and necessary costs for the establishment of a court-supervised program of medical monitoring and diagnostic testing through equitable and/or injunctive.

V. CLASS ALLEGATIONS

387. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of themselves and, under Federal Rules of Civil Procedure 23(a), (b)(2), (b)(3), (g), and (c)(4), as representatives of the classes. Specifically, the Class consists of the following:

> **Nationwide Class**: All persons in the United States who have used a Recalled Device at least 30 times.

388. Alternatively, and in addition, Plaintiffs seek certification on behalf of subclasses defined as more fully set forth below and collectively referred to as the "State Subclasses."

389. Plaintiff Pendleton seeks certification on behalf of a subclass defined as follows ("Arizona Subclass"):

> **Arizona Subclass**: All persons in Arizona who have used a

Recalled Device at least 30 times.

390. Plaintiffs Autry and Melcher seek certification on behalf of a subclass defined as follows ("Arkansas Subclass"):

> **Arkansas Subclass**: All persons in Arkansas who have used a Recalled Deviceat least 30 times.

391. Plaintiffs Bailey, DiJohn, and Nielson seek certification on behalf of a subclass defined as follows ("California Subclass"):

> **California Subclass**: All persons in California who have used a Recalled Device at least 30 times.

392. Plaintiffs McDaniel and Wolff seek certification on behalf of a subclass defined as follows ("Colorado Subclass"):

> **Colorado Subclass**: All persons in Colorado who have used a Recalled Device at least 30 times.

393. Plaintiffs Leavenworth and Toscano seek certification on behalf of a subclass defined as follows ("Connecticut Subclass"):

> **Connecticut Subclass**: All persons in Connecticut who have used a Recalled Device at least 30 times.

394. Plaintiff Boyle seeks certification on behalf of a subclass defined as follows ("Delaware Subclass"):

> **Delaware Subclass**: All persons in Delaware who have used a Recalled Device at least 30 times.

395. Plaintiff Ragland seeks certification on behalf of a subclass defined as follows ("District of Columbia Subclass"):

> **District of Columbia Subclass**: All persons in District of Columbia who have used a Recalled Device at least 30 times.

396. Plaintiffs Fields, Morris, and Paris seek certification on behalf of a subclass defined

as follows ("Florida Subclass"):

> **Florida Subclass**: All persons in Florida who have used a Recalled Device at least 30 times.

397. Plaintiff McCarty seeks certification on behalf of a subclass defined as follows ("Hawaii Subclass"):

> **Hawaii Subclass**: All persons in Hawaii who have used a Recalled Device at least 30 times.

398. Plaintiff Pendleton and Wheeler seek certification on behalf of a subclass defined as follows ("Idaho Subclass"):

> **Idaho Subclass**: All persons in Idaho who have used a Recalled Device at least 30 times.

399. Plaintiffs Baran, McCarty, and Wilson seek certification on behalf of a subclass defined as follows ("Illinois Subclass"):

> **Illinois Subclass**: All persons in Illinois who have used a Recalled Device at least 30 times.

400. Plaintiff Dusza seeks certification on behalf of a subclass defined as follows ("Indiana Subclass"):

> **Indiana Subclass**: All persons in Indiana who have used a Recalled Device at least 30 times.

401. Plaintiff Abarr seeks certification on behalf of a subclass defined as follows ("Iowa Subclass"):

> **Iowa Subclass**: All persons in Iowa who have used a Recalled Device at least 30 times.

402. Plaintiffs Cathers and Fisher seek certification on behalf of a subclass defined as follows ("Kansas Subclass"):

> **Kansas Subclass**: All persons in Kansas who have used a Recalled Device at least 30 times.

403. Plaintiff Margoles seeks certification on behalf of a subclass defined as follows ("Maine Subclass"):

> **Maine Subclass**: All persons in Maine who have used a Recalled Device at least 30 times.

404. Plaintiffs Cotton and Goodall seek certification on behalf of a subclass defined as follows ("Maryland Subclass"):

> **Maryland Subclass**: All persons in Maryland who have used a Recalled Device at least 30 times.

405. Plaintiff Bellotti seeks certification on behalf of a subclass defined as follows ("Massachusetts Subclass"):

> **Massachusetts Subclass**: All persons in Massachusetts who have used a Recalled Device at least 30 times.

406. Plaintiff Boudreau seeks certification on behalf of a subclass defined as follows ("Minnesota Subclass"):

> **Minnesota Subclass**: All persons in Minnesota who have used a Recalled Device at least 30 times.

407. Plaintiff Young seeks certification on behalf of a subclass defined as follows ("Missouri Subclass"):

> **Missouri Subclass**: All persons in Missouri who have used a Recalled Device at least 30 times.

408. Plaintiff David seeks certification on behalf of a subclass defined as follows ("Montana Subclass"):

> **Montana Subclass**: All persons in Montana who have used a Recalled Device at least 30 times.

409. Plaintiffs Mills and Glaub seek certification on behalf of a subclass defined as follows ("Nebraska Subclass"):

> **Nebraska Subclass**: All persons in Nebraska who have used a Recalled Device at least 30 times.

410. Plaintiff Lemus seeks certification on behalf of a subclass defined as follows ("Nevada Subclass"):

> **Nevada Subclass**: All persons in Nevada who have used a Recalled Device at least 30 times.

411. Plaintiff Malone seeks certification on behalf of a subclass defined as follows ("New Hampshire Subclass"):

> **New Hampshire Subclass**: All persons in New Hampshire who have used a Recalled Device at least 30 times.

412. Plaintiff Taylor seeks certification on behalf of a subclass defined as follows ("New Jersey Subclass"):

> **New Jersey Subclass**: All persons in New Jersey who have used a Recalled Device at least 30 times.

413. Plaintiffs Dennett and Rodgers seek certification on behalf of a subclass defined as follows ("New Mexico Subclass"):

> **New Mexico Subclass**: All persons in New Mexico who have used a Recalled Device at least 30 times.

414. Plaintiffs Barragan, Diaz, and Ginsberg seek certification on behalf of a subclass defined as follows ("New York Subclass"):

> **New York Subclass**: All persons in New York who have used a Recalled Device at least 30 times.

415. Plaintiffs Bartalo, King, and Margoles seek certification on behalf of a subclass defined as follows ("North Carolina Subclass"):

> **North Carolina Subclass**: All persons in North Carolina who have used a Recalled Device at least 30 times.

416. Plaintiffs Hock and Margoles seek certification on behalf of a subclass defined as

follows ("Ohio"):

> **Ohio Subclass**: All persons in Ohio who have used a Recalled Device at least 30 times.

417. Plaintiff Wells seeks certification on behalf of a subclass defined as follows ("Oklahoma"):

> **Oklahoma Subclass**: All persons in Oklahoma who have used a Recalled Device at least 30 times.

418. Plaintiffs Hibbard, Hoffman, and Sweeney seek certification on behalf of a subclass defined as follows ("Pennsylvania"):

> **Pennsylvania Subclass**: All persons in Pennsylvania who have used a Recalled Device at least 30 times.

419. Plaintiff Bonano seeks certification on behalf of a subclass defined as follows ("Puerto Rico"):

> **Puerto Rico Subclass**: All persons in Puerto Rico who have used a Recalled Device at least 30 times.

420. Plaintiff Lamontagne seeks certification on behalf of a subclass defined as follows ("Rhode Island"):

> **Rhode Island Subclass**: All persons in Rhode Island who have used a Recalled Device at least 30 times.

421. Plaintiffs Diaz and Flannery seek certification on behalf of a subclass defined as follows ("South Carolina"):

> **South Carolina Subclass**: All persons in South Carolina who have used a Recalled Device at least 30 times.

422. Plaintiffs Bakaitis and Kemp seek certification on behalf of a subclass defined as follows ("Tennessee"):

> **Tennessee Subclass**: All persons in Tennessee who have used a Recalled Device at least 30 times.

423. Plaintiffs Claunch, Malone, and Panzera seek certification on behalf of a subclass defined as follows ("Texas"):

> **Texas Subclass**: All persons in Texas who have used a Recalled Device at least 30 times.

424. Plaintiffs Humphries and Pendleton seek certification on behalf of a subclass defined as follows ("Utah"):

> **Utah Subclass**: All persons in Utah who have used a Recalled Device at least 30 times.

425. Plaintiff Martin seeks certification on behalf of a subclass defined as follows ("Vermont"):

> **Vermont Subclass**: All persons in Vermont who have used a Recalled Device at least 30 times.

426. Plaintiffs Harbor, Heilman, Rodgers, and Rose seek certification on behalf of a subclass defined as follows ("Virginia"):

> **Virginia Subclass**: All persons in Virginia who have used a Recalled Device at least 30 times.

427. Plaintiffs Lopez and Peebles seek certification on behalf of a subclass defined as follows ("Washington"):

> **Washington Subclass**: All persons in Washington who have used a Recalled Device at least 30 times.

428. Plaintiffs Caling and Hamlin seek certification on behalf of a subclass defined as follows ("West Virginia"):

> **West Virginia Subclass**: All persons in West Virginia who have used a Recalled Device at least 30 times.

429. Excluded from the Class are: (a) Defendants and their employees, officers, and directors; and (b) the Judge(s) assigned to this case.

430. Together, the Nationwide Class and the Subclasses shall collectively be referred to herein as the "Class."

431. As alleged throughout this Complaint, Defendants engaged in uniform and standardized conduct towards the Class. Defendants did not differentiate, in its degree of care or candor, its actions or inactions or in the content of its statements or omissions, among individual Class members. The objective facts on these subjects are the same for all Class members. Within each Claim for Relief asserted by the respective Classes, the same legal standards govern. Additionally, many states share the same legal standards and elements of proof, facilitating the certification of multi-state classes for some or all of the claims.

432. No actual conflict of laws exists between the laws of Plaintiffs' home states, and the laws of Class members' states. Or alternatively, any potential conflict is a false one. The lack of conflict, or the false conflict, between the laws of Plaintiffs' home states and the laws of Class members' states means it is appropriate to certify the Class under the laws of the aforementioned states, District of Columbia, and District of Puerto Rico.

433. Plaintiffs reserve the right to adjust, modify, or narrow the Class prior to class certification.

434. The rights of each member of the Class were violated in a similar fashion based upon Philips' uniform actions.

435. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. The proposed Class contains at least millions of individuals who used a Recalled Device. The Class is therefore sufficiently numerous to make joinder impracticable, if

not impossible. The precise number of Class members is unknown to Plaintiffs at this time, but the Class members are readily ascertainable and can be identified by Philips' records and records of third parties, such as durable medical equipment providers.

b. Existence and Predominance of Common Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

i. Whether Defendants were negligent in manufacturing and selling the Recalled Devices;

ii. Whether Defendants failed to warn consumers regarding the risks of the Recalled Devices;

iii. Whether Defendants are strictly liable for the manufacture and sale of the Recalled Devices;

iv. Whether Philips breached the express warranties to Plaintiffs and the Class;

v. Whether Philips breached its implied warranties to Plaintiffs and the Class;

vi. Whether the chemicals in or emitted from the polyester-based polyurethane foam in the Recalled Devices are proven hazardous substances;

vii. Whether Plaintiffs and Class members have been exposed to components of the polyester-based polyurethane foam in the Recalled Devices;

viii. Whether Plaintiffs and Class members are at an increased risk of illness, disease, or disease process because of their exposure to components of the polyester-based polyurethane foam in the Recalled Devices;

ix. Whether early detection of illness, disease or disease process will provide

benefits to Plaintiffs and Class members; and

x. The appropriate nature of class-wide equitable relief.

c. Typicality: Plaintiffs' claims are typical of the claims of all members of the Class. Plaintiffs and Class members all suffered the same type of harm, including exposure to the Foam Toxins; and increased risk of developing illness, disease, or disease process that have not yet become manifest or been recognized. Plaintiffs bring claims under the same legal and remedial theories as the class. Plaintiffs' claims arise out of the same set of facts and conduct as the Class members.

d. Adequacy: Plaintiffs are adequate representatives of the Class because their interests do not conflict with the interests of the Class that they seek to represent; they have retained counsel competent and highly experienced in complex class action litigation and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiffs and their counsel.

e. Rule 23(b)(2): Defendants have acted on grounds that apply generally to Class members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Classes as a whole. Each named Plaintiff and Class Representative has suffered exposure to Foam Toxins at levels sufficient to necessitate the medical monitoring and other relief sought in this Complaint, and can establish such sufficiency through common proof and evidence.

f. Predominance and Superiority: Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class members, and a class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiffs and the Class. Each named Plaintiff and Class Representative has suffered exposure to

Foam Toxins at levels sufficient to necessitate the medical monitoring and other relief sought in this Complaint, and can establish such sufficiency through common proof and evidence. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Philips' and PolyTech's conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court. Plaintiffs' counsel, highly experienced in product liability litigation, consumer litigation, class actions, and federal court litigation, foresee the efficient management of this case as a class action.

g. Rule 23(c)(4) Issues Class: To the extent the Court determines there are material differences in the relevant laws and that such differences present class manageability issues precluding Independent Claim and/or Remedy class certification for all purposes, Plaintiffs submit that an Independent Claim and a Remedy issue class is appropriate for determination of common material fact issues in the case, and are predicates for the entitlement to medical monitoring (such as exposure, contamination, misconduct, increased risk, existence of testing and benefit of testing, among others).

VI. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

436. The running of any statute of limitations has been equitably tolled by Defendants'

fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiffs and physicians the true risks associated with the Recalled Devices.

437. As a result of Defendants' actions, Plaintiffs were unaware, and could not have reasonably known or learned through reasonable diligence, that the Recalled Devices were defective and exposed users to the risks and harms set forth here and that those risks and harms were the direct and proximate result of Defendants' acts and omissions.

438. Plaintiffs did not have the technical, scientific, or medical knowledge and information sufficient to ascertain the cause of their injury prior to learning of the recall and the basis for the recall.

VII. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

NEGLIGENCE
(Individually, on Behalf of the Class, and on behalf of the Subclasses)

439. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein.

440. This claim is brought against the Philips Defendants and the PolyTech Defendants.

441. Philips and PolyTech owed a duty to Plaintiffs and Class members to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of the Recalled Devices.

442. Philips and PolyTech owed a duty to Plaintiffs and Class members to ensure that the Recalled Devices it sold in the United States were safe, did not expose patients using the devices to toxic substances, and/or complied with current best manufacturing practices and regulatory requirements.

443. Philips and PolyTech owed a duty of care to Plaintiffs and Class members; because they were the foreseeable, reasonable, and probable users of the Recalled Devices. Philips and PolyTech knew, or should have known, that the Recalled Devices were not safe, exposed their users to toxic and carcinogenic compounds, and/or did not comply with best manufacturing practices and regulatory requirements. Philips and PolyTech were in the best position to uncover and remedy these shortcomings.

444. Philips and PolyTech negligently designed and manufactured the Recalled Devices, causing patients using the Recalled Devices to be exposed to the Foam Toxins, which are carcinogenic and/or toxic.

445. Philips and PolyTech failed to discharge its duties of reasonable care. Philips and PolyTech inadequately conducted or oversaw the design, manufacture, testing, labeling, distribution, marketing, warnings, disclosures, and sale of the Recalled Devices. Philips and PolyTech knew that the aforesaid wrongdoing would injure Plaintiffs and Class members.

446. Philips and PolyTech negligently failed to promptly and immediately warn and disclose to Plaintiffs and Class members, and the medical and regulatory communities, of the potential and actual danger posed by the PE-PUR foam in the Recalled Devices as soon as it was discovered, delaying notice of this harmful and potentially fatal toxic exposure to carcinogens and thus causing continued exposure to the carcinogenic and/or hazardous compounds, and delaying necessary medical testing, examinations, surveillance, and treatment.

447. Philips' and PolyTech's negligent or grossly negligent conduct created and then exacerbated an unreasonable and dangerous condition for Plaintiffs and Class members.

448. Philips and PolyTech acted with recklessness and willful and wanton disregard for the health of Plaintiffs and Class members.

449. Philips' and PolyTech's unreasonable, negligent actions and inactions were taken or not taken with willful and wanton disregard for the health of Plaintiffs and Class members and created a foreseeable risk of harm to Plaintiffs and Class members.

450. As a direct and proximate result of Philips' and PolyTech's misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

451. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

452. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

453. Plaintiffs also seek such further relief as the Court deems equitable and just.

SECOND CLAIM FOR RELIEF

NEGLIGENCE PER SE
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

454. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein.

455. This claim is brought against the Philips Defendants.

456. At all times, Philips had an obligation to comply with applicable statutes and regulations, including relevant and applicable statues and regulations promulgated by the FDA.

457. Philips utilized the 510(k) process to receive clearance for each of its Recalled Devices except the E30 ventilator which was marketed under an EUA.

458. Philips' actions as described herein violated applicable statutes and regulations related to the 510(k) application process, including but not limited to 21 C.F.R. § 807 *et seq.*, and parallel state law requirements.

459. Philips' actions as described herein violated applicable statutes and regulations related to its duty to monitor, investigate, evaluate and timely report issues with foam degradation, including 21 C.F.R. part 803 and 21 C.F.R. § 820.198, and parallel state law requirements.

460. Plaintiffs are within the class of persons that these statutes and regulations are intended to protect.

461. Plaintiffs' injuries and/or symptoms are the type of harm that these statutes and regulations are intended to prevent.

462. Philips' violations of the foregoing statutes and regulations, among others, constitutes negligence per se.

463. As a direct and proximate result of Philips' and PolyTech's misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

464. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other

necessary medical consultations for the early detection of illness, disease and disease process.

465. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

466. Plaintiffs also seek such further relief as the Court deems equitable and just.

THIRD CLAIM FOR RELIEF

NEGLIGENT MISREPRESENTATION AND OMISSION (Individually, on Behalf of the Class, and on Behalf of the Subclasses)

467. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein.

468. This claim is brought against the Philips Defendants.

469. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew, or should have known, that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers, including Plaintiffs, Class members, and their physicians, because to do otherwise would have resulted in users seeking safer alternatives to treat their breathing issues.

470. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were

particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

471. Philips had a duty to tell Plaintiffs and the public the truth about the risks and harms associated with the Recalled Devices.

472. Philips concealed from Plaintiffs and Class members and failed to disclose to them material information regarding the serious health risks posed to users of the Recalled Devices by, among other things, failing to include material information in its packaging, labels, advertisements, promotional materials, websites, and other communications and disclosures

473. Philips failed to advise Plaintiffs of the material fact that the Recalled Devices posed serious health risks to users. Philips concealed from Plaintiffs information regarding the adverse health effects posed by the Recalled Devices. Philips misrepresented to Plaintiffs that the Recalled Devices were safe for use.

474. Philips was under a duty to disclose to, among others, Plaintiffs, Class members, and their physicians, the serious health risks posed to users because: (a) Philips was in a superior position to Plaintiffs to know the risks associated with the use of the Recalled Devices; (b) Philips was in a superior bargaining position to Plaintiffs in determining whether or not to disclose or conceal information regarding the Recalled Devices in its packaging, labels, advertising, and websites; (c) Philips made representations regarding the safety of the Recalled Devices and had a duty to fully disclose all facts related to the serious health risks to users posed by the Recalled Devices, once Philips became aware of such serious health risks; (d) Philips knew that the Plaintiffs, Class members, or their physicians could not reasonably have been expected to learn or discover the serious health risks posed by use of the Recalled Devices prior to using the Recalled Devices, given the representations, concealed material information, and omissions by Philips in

their packaging, labels, advertising, and websites; and (e) Philips had a duty to disclose information related to the health and safety of its products.

475. Philips breached its duty by falsely representing to Plaintiffs, Class members, their physicians, and the public that the Recalled Devices were safe for use when Philips knew or should have known that the Recalled Devices were defective and had not been properly or adequately tested.

476. Philips failed to exercise ordinary care in the representation of the Recalled Devices during its manufacturing, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, in that Philips negligently misrepresented the safety and efficacy of the devices.

477. As a direct and proximate result of Philips' misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

478. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

479. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

480. Plaintiffs also seek such further relief as the Court deems equitable and just.

FOURTH CLAIM FOR RELIEF

MEDICAL MONITORING
(Individually, on Behalf of the Class, and on behalf of the Colorado, Connecticut, Delaware, District of Columbia, Florida, Massachusetts, Montana, New Hampshire, Pennsylvania, Utah, and West Virginia Subclasses)

481. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein.

482. This claim is brought against the Philips Defendants and the PolyTech Defendants.

483. Plaintiffs bring an independent claim of medical monitoring against Philips and PolyTech. Plaintiffs bring this claim on behalf of themselves and Class members residing in the following U.S. jurisdictions: Colorado, Connecticut, Delaware, the District of Columbia, Florida, Massachusetts, Montana, New Hampshire, Pennsylvania, Utah, and West Virginia. If the court finds that an independent claim for medical monitoring does not lie, Plaintiffs and Class members in these states claim the cost of medical monitoring as an element of damages. Should the relevant law change in any U.S. jurisdiction not mentioned above, Plaintiffs reserve the right to amend accordingly.

484. As a proximate result of Philips' and PolyTech's acts and omissions, Plaintiffs and Class members have suffered exposure to proven hazardous substances and as a result are at an increased risk of developing cancer and other illnesses, diseases, and disease processes above the normal base-level risk.

485. As alleged above, the Recalled Devices contained defective PE-PUR foam that exposed patients using the devices to the Foam Toxins, which are known to cause cancer and other illnesses, diseases, and disease process in humans.

486. Plaintiffs and Class members may not develop cancer or various adverse health effects for many years.

487. Plaintiffs and Class members are at an increased risk as they, persistently inhaled, consumed, and/or ingested the Foam Toxins for extended periods of time (some as many as several years) and as a result were exposed to critical levels of multiple toxic and carcinogenic compounds.

488. Upon information and belief and based upon the internal and external investigations now made public, the Plaintiffs and Class members are at a substantially increased risk as they were exposed to multiple Foam Toxins.

489. The Foam Toxins are proven hazardous and toxic substances that are known to cause cancer and other illnesses, diseases, and disease process in humans.

490. Plaintiffs and Class members are at an increased risk of, inter alia, cancer and other serious illness and disease, as they were exposed to, inhaled, consumed, and/or ingested the Foam Toxins in quantities, and over periods of time sufficient to establish levels of exposure that are hazardous to health, and sufficient to cause cancer and other serious ailments, or increase the risk of developing cancer and other serious ailments.

491. The exposure was solely and proximately caused by Philips' and PolyTech's acts and omissions, including: their failure to adequately design and manufacture their Recalled Devices to satisfy applicable standards imposed by law and regulation; their failure to address known issues with the PE-PUR foam during quality control testing; their material misrepresentations, false statements, and other deceptive practices in continuing to claim that the Recall Devices were safe for use.

492. Philips and PolyTech owed duties to the Plaintiffs and Class members: to ensure and warrant that the Recalled Devices were indeed designed and manufactured to satisfy applicable

standards imposed by law and regulation; to disclose to Class members any defect or other potential health hazard known or discoverable by Philips and PolyTech; and to ensure that the Recalled Devices were safe, reliable, and non-hazardous for human consumption-their intended purpose.

493. As alleged above, Philips' and PolyTech's negligent acts and omissions resulted in, among other things, an increased risk of developing cancer or other serious health condition for all Plaintiffs and Class members. As one example, cancer is a serious disease that causes life-threatening illness and debilitating cellular, genetic, and physical injury. Technology, analytical tools, test and/or monitoring procedures exist and are readily available to detect latent or unrecognized cancer and other deleterious health conditions in Plaintiffs and class members. These technologies, tools tests and/or monitoring procedures are accepted and widely used by the scientific and medical community. The existing scientific methods include, but are not limited, to blood and laboratory tests; physical examinations; imaging; colonoscopies, endoscopies, and other similar methods for examination; biopsies; pathologic, histologic, and oncologic evaluations; and oncologic, histologic, surgical and other necessary medical consultations.

494. Early detection of cancer and other serious health conditions in Plaintiffs and Class members is one of the best, and sometimes the only, means to treat cancer and other ailments such that they do not cause lasting, permanent harm, illness, or death.

495. Early detection of cancer and other serious health conditions in Plaintiffs and class members necessarily allows them to avail themselves of myriad forms of treatment, each of which is capable to altering the course of the illness, such as bringing the cancer into remission, removal of any malignant tumors, and other treatment to alleviate the harm.

496. The tests for the early detection of cancer and other serious health conditions must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles. Because cancer screenings associated with the Foam Toxins may not be conducted with the type, timing, scope and frequency necessary to identify cancer in the absence of exposure to the Foam Toxins, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Further, Plaintiffs and Class members require more frequent screenings not within the purview of routine medical exams.

497. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

498. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

499. Plaintiffs also seek such further relief as the Court deems equitable and just.

FIFTH CLAIM FOR RELIEF

PRODUCTS LIABILITY-DESIGN DEFECT
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

500. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as is fully set forth herein.

501. This claim is brought against the Philips Defendants and the PolyTech Defendants.

502. At all times herein mentioned, Philips and PolyTech were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, which are defective and unreasonably dangerous.

503. Plaintiffs were foreseeable users of the Recalled Devices and Philips and PolyTech

knew that Plaintiffs would use the Recalled Devices.

504. The Recalled Devices are defective in design because the PE-PUR foam comprising part of the devices is subject to degradation and off-gassing and the PE-PUR foam contains toxic and carcinogenic materials. The Recalled Devices release particles and off-gas chemicals, including TDA, TDI, DEG. These chemicals and particles are then inhaled and ingested by Plaintiffs using the Recalled Devices and cause, among other problems, cancer, kidney injuries, cardiac injuries, headaches, irritation of the skin, eye, and respiratory tract, inflammation, respiratory issues, asthma, adverse effects to organs, hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects.

505. Philips and PolyTech knew or should have known that the defective conditions of the Recalled Devices made the Recalled Devices unreasonably dangerous to Plaintiffs.

506. The Recalled Devices were unreasonably dangerous when used by ordinary users such as Plaintiffs who used the Recalled Devices as they were intended to be used.

507. The Recalled Devices are dangerous to an extent beyond what would be contemplated by the ordinary user of the Recalled Devices.

508. The defective condition of the subject device rendered it unreasonably dangerous and/or not reasonably safe, and the device was in this defective condition at the time it left the hands of Philips. The Recalled Devices reached Plaintiffs without substantial change in the condition in which they were designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

509. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable diligence, the defective nature of the subject devices. Further, in no way could Plaintiffs have known that Philips and PolyTech had designed, developed, and manufactured

the subject devices in a way as to make the risk of harm outweigh any benefits.

510. Safer alternative machines and designs were available which did not have an unreasonable risk of harm as the Recalled Devices and their unsafe PE-PUR foam, for example devices manufactured by other manufacturers.

511. At the time the Recalled Devices left Philips' possession and later were used by Plaintiffs, the Recalled Devices were in a condition that made them unreasonably dangerous to Plaintiffs.

512. The Recalled Devices used by Plaintiffs were expected to and did reach Plaintiffs without substantial change in the condition in which the Recalled Devices were manufactured, sold, distributed, and marketed by Philips and PolyTech.

513. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the Recalled Devices were intended to be used.

514. Philips and PolyTech researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed the defective Recalled Devices which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiffs, and Philips is therefore strictly liable for the injuries sustained by Plaintiffs.

515. As a direct and proximate result of Philips' and PolyTech's misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

516. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

517. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

518. Plaintiffs also seek such further relief as the Court deems equitable and just.

SIXTH CLAIM FOR RELIEF

NEGLIGENT DESIGN
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

519. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein.

520. This claim is brought against the Philips Defendants and the PolyTech Defendants.

521. At all times herein mentioned, Philips and PolyTech were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, which are defective and unreasonably dangerous.

522. At all times relevant to this action, Philips and PolyTech had a duty to design, manufacture, formulate, test, package, label, produce, create, make, construct, assemble, market, advertise, promote, distribute, and sell the Recalled Devices with reasonable and due care for the safety and well-being of users, including Plaintiffs who used the Recalled Devices.

523. Plaintiffs were foreseeable users of the Recalled Devices, and Philips and PolyTech knew that Plaintiffs would use the Recalled Devices.

524. It was foreseeable that the Recalled Devices would be used with the Accessory Humidifiers contributing to humidity; and that they could be used in many climates, and stored in

very warm settings, as noted by their own environmental specifications, with said condition contributing to rapid foam degradation.

525. The Recalled Devices are defective in design because the PE-PUR foam comprising part of the devices is subject to degradation and the PE-PUR foam contains toxic and carcinogenic materials. The Recalled Devices release the Foam Toxins, which are then inhaled and ingested by patients using the Recalled Devices. The Foam Toxins cause, among other problems, cancer, kidney injuries, cardiac injuries, headaches, irritation of the skin, eye, and respiratory tract, inflammation, respiratory issues, asthma, adverse effects to organs, hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects.

526. The foreseeable risks of using the Recalled Devices, particularly respiratory illnesses up to and including death, significantly outweigh the benefits conferred upon patients using the subject devices.

527. Philips and PolyTech knew or should have known that the defects of the Recalled Devices made the Recalled Devices unreasonably dangerous

528. Philips and PolyTech continued to manufacture and distribute the Recalled Devices after Philips and PolyTech knew or should have known of the Recalled Devices adverse effects or the availability of safer designs.

529. The Recalled Devices were unreasonably dangerous when used by Plaintiffs, who followed the instructions provided by Philips and used the Recalled Devices with common knowledge of their characteristics and according to their common usage.

530. At the time the Recalled Devices left Philips' possession and later were used by Plaintiffs, the Recalled Devices were in a condition that made them unreasonably dangerous to Plaintiffs.

531. The Recalled Devices used by Plaintiffs were expected to and did reach Plaintiffs without substantial change in the condition in which the Recalled Devices were manufactured, sold, distributed, and marketed by Philips and PolyTech.

532. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the Recalled Devices were intended to be used.

533. Philips and PolyTech had superior knowledge of the Recalled Devices and owed a duty of care to Plaintiffs.

534. Reasonable alternative designs existed for the subject devices which would have eliminated or reduced the risk of inhalation of carcinogenic materials and VOCs.

535. Philips and PolyTech failed to exercise reasonable and due care under the circumstances and breached their duty of care.

536. As a direct and proximate result of Philips' and PolyTech's misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

537. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

538. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

539. Plaintiffs also seek such further relief as the Court deems equitable and just.

SEVENTH CLAIM FOR RELIEF
STRICT LIABILITY - FAILURE TO WARN
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

540. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein.

541. This claim is brought against the Philips Defendants and the PolyTech Defendants.

542. Philips and PolyTech designed, manufactured, and sold the Recalled Devices.

543. Plaintiffs were foreseeable users of the Recalled Devices.

544. The Recalled Devices are defective because the PE-PUR foam comprising part of the devices is subject to degradation and off-gassing and the PE-PUR foam contains toxic and carcinogenic materials. The Recalled Devices release chemicals and particles, including but not limited to TDA, TDI, DEG. These chemicals and particles are then inhaled and ingested by Plaintiffs using the Recalled Devices and cause, among other problems, cancer, kidney injuries, cardiac injuries, headaches, irritation of the skin, eye, and respiratory tract, inflammation, respiratory issues, asthma, adverse effects to organs, hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects.

545. Philips and PolyTech knew that the defective condition of the Recalled Devices made the devices unreasonably dangerous to users such as Plaintiffs.

546. The Recalled Devices are dangerous when used by ordinary users who used the devices as intended.

547. The Recalled Devices are dangerous to an extent beyond that contemplated by ordinary users of the devices.

548. Philips and PolyTech knew or should have known of the defects in the Recalled Devices at the time Philips and PolyTech sold or provided the Recalled Devices that were used by

Plaintiffs.

549. At the time the Recalled Devices left Philips' possession, the Recalled Devices were defective and in a condition that made them unreasonably dangerous to Plaintiffs.

550. At the time Plaintiffs used the Recalled Devices, the devices were defective and in a condition that made them unreasonably dangerous to Plaintiffs.

551. The Recalled Devices used by Plaintiffs was expected to and did reach Plaintiffs without substantial change in the condition in which the devices were manufactured, sold, distributed, and marketed by Philips and PolyTech.

552. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the devices were intended to be used.

553. The Recalled Devices are defective because Philips and PolyTech failed to warn or instruct that the PE-PUR foam in the Recalled Devices can degrade and emit dangerous and carcinogenic Foam Toxins and particles, posing a serious risk to users.

554. Philips and PolyTech further failed to warn or instruct that the Recalled Devices had not been adequately or properly tested.

555. The warning and instructions that accompanied the Recalled Devices failed to provide the level of information that ordinary consumers, including Plaintiffs, would expect when using the product in a manner reasonably foreseeable to Philips and PolyTech.

556. Philips and PolyTech further failed to warn or instruct that the Recalled Devices, when used in conjunction with the Accessory Humidifiers, would hasten the degradation of the foam and make the Recalled Devices especially dangerous.

557. Philips and PolyTech further failed to warn or instruct that the Recalled Devices should not be stored in warm climates and conditions, and that warm temperatures and humidity would hasten the degradation of the foam, and make the Recalled Devices especially dangerous.

558. Philips and PolyTech further failed to warn or instruct that the Recalled Devices should not be used in conjunction with the SoClean ozone cleaning system which Philips now claims can hasten or cause the degradation of the foam and make the Recalled Devices especially dangerous.

559. Had Plaintiffs received proper or adequate warnings or instructions as to the risks of using the Recalled Devices, Plaintiffs would not have used the Recalled Devices.

560. Had Plaintiffs received proper or adequate warnings or instructions as to the storage, climate and cleaning conditions and protocols, they would have heeded such warnings to mitigate the risk of premature foam degradation.

561. Philips and PolyTech researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed the defective Recalled Devices which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiffs, and Philips and PolyTech are therefore strictly liable for the injuries sustained by Plaintiffs.

562. As a direct and proximate result of Philips' and PolyTech's misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

563. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

564. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

565. Plaintiffs also seek such further relief as the Court deems equitable and just.

EIGHTH CLAIM FOR RELIEF

NEGLIGENT FAILURE TO WARN
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

566. Plaintiffs reallege and incorporate by reference the allegations set forth in the Complaint as is fully set forth herein.

567. This claim is brought against the Philips Defendants and the PolyTech Defendants.

568. Plaintiffs bring this claim on behalf of themselves and all Class members residing in all U.S. jurisdictions.

569. Even though the Recalled Devices are subject to degradation release of the Foam Toxins—which cause, among other problems, cancer, kidney injuries, cardiac injuries, headaches, irritation of the skin, eye, and respiratory tract, inflammation, respiratory issues, asthma, adverse effects to organs, hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects— Philips and PolyTech failed to warn Plaintiffs and Class members, and the medical and regulatory communities as soon as this risk was suspected or known.

570. Philips' and PolyTech's failure to warn was intentional, reckless, and in wanton and willful disregard for the rights and health of Plaintiffs and Class members, causing exposure to the Foam Toxins—as well as delay of diagnosis and treatment.

571. To the extent privity may be required, Plaintiffs and Class members can establish privity with Philips and PolyTech or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement. Plaintiffs and Class members relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

572. Alternatively, Plaintiffs and Class members were foreseeable third-party beneficiaries of Philips' and PolyTech's sale of the Recalled Devices.

573. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the devices were intended to be used.

574. As a direct and proximate result of Philips' and PolyTech's misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

575. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

576. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

577. Plaintiffs also seek such further relief as the Court deems equitable and just.

NINTH CLAIM FOR RELIEF

NEGLIGENT RECALL / NEGLIGENT FAILURE TO RECALL (Individually, on Behalf of the Class, and on Behalf of the Subclasses)

578. Plaintiffs reallege and incorporate by reference the allegations set forth in the Complaint as though fully set forth herein.

579. This claim is brought against the Philips Defendants.

580. Despite being aware of the Defect in the Recalled Devices as far back as 2008, Philips did not initiate a recall of the Recalled Devices until June 14, 2021.

581. At all times relevant hereto, Philips manufactured, marketed, distributed, and sold the Recalled Devices.

582. As set forth in detail above, as far back as 2008 (and in no event later than 2015), Philips knew or reasonably should have known that the Recalled Devices were defective and exposed users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam in the Recalled Devices.

583. Despite that knowledge, Philips did not attempt to recall or retrofit the Recalled Devices prior to June 14, 2021, long after any reasonable manufacturer, distributor and/or seller under the same circumstances would have instituted a recall or retrofitted the Recalled Devices.

584. Because of the delay in instituting a recall, Plaintiffs continued to use the Recalled Devices when, without their knowledge, they were being exposed to substantial health risks.

585. Had Philips instituted a recall when the risks to potential users of using the Recalled Devices were first made clear, Plaintiffs would have not used the defective devices and would have sought alternative methods to treat their breathing-related illnesses.

586. Philips was aware that Plaintiffs would make such a choice. That is why Philips waited until it announced the launch of the DreamStation 2, which does not contain PE-PUR foam,

before it publicly disclosed that its previous generation of DreamStation products and other Recalled Devices posed serious health risks to users, and before Philips finally instituted a recall.

587. Even after Philips finally announced it was instituting a voluntary recall of the Recalled Devices, it implemented the Recall negligently.

588. Royal Philips took charge of and responsibility for the Recall. Royal Philips has interfaced with regulatory agencies in the U.S. and worldwide, but has not adequately notified users and their doctors about the recall or the options for obtaining a replacement device.

589. First, when the Recall was announced on June 14, 2021, Philips did not adequately provide notice to users or their doctors about the risks of using the Recalled Devices, nor did Philips offer users of the Recalled Devices any option for a replacement device. In fact, the FDA issued a Notification Order to Philips under § 518(a) of the FDCA, documenting that the FDA "on multiple occasions has informed Philips that FDA was concerned that Philips' efforts to notify patients and consumers, healthcare providers, and consignees regarding the recall have been insufficient," and has expressed concern that "it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products."[414]

590. Then, when Philips received authorization from the FDA to begin a repair and/or replacement process for affected DreamStation devices in the United States, Philips estimated that it would take a year to complete the program. Philips was aware that this time frame was untenable for patients, many of whom relied on the machines to treat medical conditions.

591. In addition, DreamStation customers were not given any specifics as to how the replacement program would work nor were they told when they might receive a replacement

[414] 518(a) Notification Order (Exhibit "136" hereto), at 6.

device (a significant factor for users who, again, relied on the machines for medical conditions) nor were their treating physicians given any meaningful guidance by Philips.

592. Still, the repair/replacement program only applied to affected DreamStation devices and did not impact any of the other Recalled Devices. Later, Philips instituted a repair program for the Trilogy devices, which has only just recently begun.

593. Despite the estimated one-year timeline originally announced by Philips to replace recalled DreamStation devices, Philips has not performed the Recall according to its own projections, and many users are still waiting for repaired or replaced devices.

594. In issuing a voluntary recall, Philips assumed duties to exercise reasonable care in issuing and implementing the Recall. Philips' conduct constitutes a breach of its duties by failing to adequately warn and notify users of the risks of using the Recalled Devices and failing to promptly replace the Recalled Devices.

595. As a result of Philips breach of duty, Plaintiffs continued to use and purchase additional Recalled Devices. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the devices were intended to be used.

596. As a direct and proximate result of Philips' misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

597. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation

of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

598. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

599. Plaintiffs also seek such further relief as the Court deems equitable and just.

TENTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (Individually, on Behalf of the Class, and on Behalf of the Subclasses)

600. Plaintiffs reallege and incorporate by reference the allegations set forth in the Complaint as though fully set forth herein.

601. This claim is brought against the Philips Defendants.

602. The implied warranty of merchantability, contained in U.C.C. § 2-314, has been codified in each state. *See, e.g.*, Ala. Code § 7-2-314, *et seq.*; Alaska Stat. § 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. § 47-2314, *et seq.*; Ark. Code Ann. § 4-2-314, *et seq.*; Cal. Com. Code § 2314, *et seq.*; Colo. Rev. Stat. § 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. § 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, § 2-314, *et seq.*; D.C. Code Ann. § 28:2-314, *et seq.*; Fla. Stat. Ann. § 672.314, *et seq.*; O.C.G.A. § 11-2-314, *et seq.*; Haw. Rev. Stat. § 490:2-314, *et seq.*; Idaho Code § 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. § 26-1-2-314, *et seq.*; Iowa Code Ann. § 554.2314, *et seq.*; Kan. Stat. Ann. § 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. § 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, § 2-314, *et seq.*; Md. Code Ann., Com. Law § 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, § 2-314, *et seq.*; Mich. Comp. Laws Ann. § 440.2314, *et seq.*; Minn. Stat. Ann. § 336.2-314, *et seq.*; Miss. Code Ann. § 75-2-314, *et seq.*; Mo. Rev. Stat. § 400.2-314, *et seq.*; Mont. Code Ann. § 30-2-314, *et seq.*; Neb. Rev. Stat. § 2-314, *et seq.*; Nev. Rev. Stat. § 104.2314, *et seq.*; N.H. Rev. Stat. Ann. § 382-

A:2-314, *et seq.*; N.J. Stat. Ann. § 12A:2-314, *et seq.*; N.M. Stat. Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law § 2-314, *et seq.*; N.C. Gen. Stat. Ann. § 25-2-314, *et seq.*; N.D. Cent. Code § 41-02-31, *et seq.*; Ohio Rev. Code Ann. § 1302.27, *et seq.*; Okla. Stat. tit. 12A, § 2-314, *et seq.*; Or. Rev. Stat. § 72.3140, *et seq.*; 13 Pa. Stat. Ann. § 2314, *et seq.*; R.I. Gen. Laws § 6A-2-314, *et seq.*; S.C. Code Ann. § 36-2-314, *et seq.*; S.D. Codified Laws § 57A-2-314, *et seq.*; Tenn. Code Ann. § 47-2-314, *et seq.*; Tex. Bus. & Com. Code § 2.314, *et seq.*; Utah Code Ann. § 70A-2-314, *et seq.*; Va. Code Ann. § 8.2-314, *et seq.*; Vt. Stat. Ann. tit. 9A, § 2-314, *et seq.*; Wash. Rev. Code § 62A.2-314, *et seq.*; W. Va. Code § 46-2-314, *et seq.*; Wis. Stat. Ann. § 402.314, *et seq.*; and Wyo. Stat. Ann. § 34.1-2-314, *et seq*.

603. Philips has, at all times, been a merchant with respect to the products which were sold to Plaintiffs and the Class, under U.C.C. §§ 2-104 and 2-314, as codified in each state; and was in the business of selling such products.

604. Pursuant to U.C.C. § 2-314, as codified in each state, each Recalled Device sold by Philips comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used.

605. The ordinary intended purpose of the Recalled Devices—and the purpose for which they were marketed, promoted, and sold—was to help people breathe. The Recalled Devices were not fit for that use—or any other use—because using the Recalled Device for breathing assistance exposed the user to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. When used as intended, the Recalled Devices were unsuitable and unsafe for personal use.

606. Philips breached its implied warranty of merchantability because the Recalled Devices were not in merchantable condition when sold, were defective when sold, and/or did not possess even the most basic degree of fitness for ordinary use.

607. Plaintiffs and the members of the Class were injured as a direct and proximate result of Philips' breach of its implied warranty of merchantability because, had they been aware of the unmerchantable condition of the Recalled Devices, they would not have used them and jeopardized their health.

608. To the extent that privity may be required, Plaintiffs and the members of the Class can establish privity with Philips, or, alternatively, can establish that they fall into an exception to a privity requirement.

609. Plaintiffs and the members of the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

610. Plaintiffs and the members of the Class were foreseeable and intended third-party beneficiaries of Philips' sale of the Recalled Devices, and/or of contracts between Philips and the distributors or sellers of the Recalled Devices.

611. The Recalled Devices are products such medical devices that affect human health and life; and therefore, they implicate the broad public policy of protecting human health and life.

612. Enforcement of a privity requirement would unfairly prejudice Plaintiffs and the members of the Class, who relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

613. In addition, any purported durational limit to the implied warranty of merchantability would be procedurally and substantively unconscionable and otherwise unenforceable.

614. An attempted durational limit would be procedurally unconscionable because Philips unilaterally imposed the time limitation on the implied warranty of merchantability, without affording Plaintiffs and the Class any bargaining authority. Indeed, the limitation was

drafted by Philips, without any input or consent from Plaintiffs and the Class, and it was presented to Plaintiffs and the Class as a settled term in the User Manual issued for each Recalled Device. As such, Plaintiffs and the Class had no meaningful choice in setting any temporal limitation on the warranty.

615. Such a limitation would be substantively unconscionable because there was a substantial disparity in the parties' relative bargaining power. As Plaintiffs allege, prior to and at the time it sold the Recalled Devices to Plaintiffs and the Class, Philips was aware of the latent defect regarding PE-PUR foam degradation in the Recalled Devices. Yet, Philips suppressed information concerning the latent defect from Plaintiffs and the Class. If a durational limit existed, it would mean Philips had abused its superior knowledge of the Defect to manipulate the temporal limits of the implied warranty of merchantability in such a manner so that it could avoid coverage relating to the latent defect while it continued manufacturing and selling the Recalled Devices containing PE-PUR foam, including to Plaintiff and the Class. Plaintiffs and the Class had no notice or ability to detect the latent defect.

616. Relatedly, due to Philips' knowing concealment of facts and information concerning the latent defect in the Recalled Devices, any purported durational limitation on the implied warranty of merchantability would be tolled or waived. Defendants' affirmative acts of concealment were designed to prevent any inquiry concerning the Recalled Devices and to induce Plaintiffs and the Class, who did not have notice of or the ability to detect the latent defect, to purchase and/or use the Recalled Devices that purportedly had the temporal limitation on the implied warranty of merchantability in place.

617. In addition, any attempt by Philips to limit the term of the implied warranty of merchantability should not be enforced given that the language purporting to set forth the limitation was not presented to Plaintiffs and the Class in a clear and conspicuous manner.

618. Plaintiffs are not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for over a year. Further, at a minimum on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements

619. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiffs and the Class reasonably expected that the Recalled Devices were safe for their ordinary and intended use.

620. As a direct and proximate result of Philips' misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

621. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

622. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

623. Plaintiffs also seek such further relief as the Court deems equitable and just.

ELEVENTH CLAIM FOR RELIEF

BREACH OF THE IMPLIED WARRANTY OF USABILITY (Individually, on Behalf of the Class, and on Behalf of the Subclasses)

624. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as if fully set forth herein.

625. This claim is brought against the Philips Defendants.

626. The implied warranty of usability arises under U.C.C. § 2-314 which has been codified in each state. *See, e.g.*, Ala. Code § 7-2-314, *et seq.*; Alaska Stat. § 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. § 47-2314, *et seq.*; Ark. Code Ann. § 4-2-314, *et seq.*; Cal. Com. Code § 2314, *et seq.*; Colo. Rev. Stat. § 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. § 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, § 2-314, *et seq.*; D.C. Code Ann. § 28:2-314, *et seq.*; Fla. Stat. Ann. § 672.314, *et seq.*; O.C.G.A. § 11-2-314, *et seq.*; Haw. Rev. Stat. § 490:2-314, *et seq.*; Idaho Code § 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. § 26-1-2-314, *et seq.*; Iowa Code Ann. § 554.2314, *et seq.*; Kan. Stat. Ann. § 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. § 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, § 2-314, *et seq.*; Md. Code Ann., Com. Law § 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, § 2-314, *et seq.*; Mich. Comp. Laws Ann. § 440.2314, *et seq.*; Minn. Stat. Ann. § 336.2-314, *et seq.*; Miss. Code Ann. § 75-2-314, *et seq.*; Mo. Rev. Stat. § 400.2-314, *et seq.*; Mont. Code Ann. § 30-2-314, *et seq.*; Neb. Rev. Stat. § 2-314, *et seq.*; Nev. Rev. Stat. § 104.2314, *et seq.*; N.H. Rev. Stat. Ann. § 382-A:2-314, *et seq.*; N.J. Stat. Ann. § 12A:2-314, *et seq.*; N.M. Stat. Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law § 2-314, *et seq.*; N.C. Gen. Stat. Ann. § 25-2-314, *et seq.*; N.D. Cent. Code § 41-02-31, *et seq.*; Ohio Rev. Code Ann. § 1302.27, *et seq.*; Okla. Stat. tit. 12A, § 2-314, *et seq.*; Or. Rev. Stat. § 72.3140, *et seq.*; 13 Pa. Stat. Ann. § 2314, *et seq.*; R.I. Gen. Laws § 6A-2-314, *et seq.*; S.C.

Code Ann. § 36-2-314, *et seq.*; S.D. Codified Laws § 57A-2-314, *et seq.*; Tenn. Code Ann. § 47-2-314, *et seq.*; Tex. Bus. & Com. Code § 2.314, *et seq.*; Utah Code Ann. § 70A-2-314, *et seq.*; Va. Code Ann. § 8.2-314, *et seq.*; Vt. Stat. Ann. tit. 9A, § 2-314, *et seq.*; Wash. Rev. Code § 62A.2-314, *et seq.*; W. Va. Code § 46-2-314, *et seq.*; Wis. Stat. Ann. § 402.314, *et seq.*; and Wyo. Stat. Ann. § 34.1-2-314, *et seq*.

627. Philips has, at all times, been a merchant with respect to the products which were sold to Plaintiffs and the Class, under U.C.C. §§ 2-104 and 2-314, as codified in each state; and was in the business of selling such products.

628. By operation of law, Philips, as the manufacturer of the Recalled Devices and as the providers of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiffs and the Class that the Recalled Devices were usable for their ordinary and intended use.

629. Such implied warranty arises under U.C.C. § 2-314(3) as adopted in each state.

630. Through usage of trade, manufacturers of medical devices, such as the Recalled Devices, impliedly warrant that their products are usable for the end consumer.

631. The ordinary intended use of the Recalled Devices was to help people breathe. The Recalled Devices were not fit for that use—or any other use—because using the Recalled Device for breathing assistance exposed the user to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. When used for their ordinary and intended use, the Recalled Devices were unsuitable and unsafe, and, thus, adulterated.

632. Philips breached its implied warranty of usability because the Recalled Devices were not usable for their ordinary and intended use and were not usable for the end consumer. At the point of sale, the Recalled Devices while appearing normal—contained the Defect rendering them unusable.

633. Philips, its agents and employees knew, or should have known, that the Recalled Devices suffered from a defect that causes negative health effects and/or places persons at risk for negative health effects to such an extent that the products are unusable.

634. Philips' Recall announcement instructed Class members to not use Recalled Devices because of the health risks illustrating that the Recalled Devices are unusable and worthless.

635. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiffs and the Class reasonably expected that the Recalled Devices were usable for their ordinary and intended use.

636. Had Plaintiffs known that Philips had breached the implied warranty of usability for their Recalled Devices, they would not have used the Recalled Devices.

637. To the extent privity may be required, Plaintiffs and the members of the Class can establish privity with Philips, or, alternatively, can establish that they fall into an exception to a privity requirement.

638. Plaintiffs and the members of the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

639. Plaintiffs and the members of the Class were foreseeable and intended third-party beneficiaries of Philips' sale of the Recalled Devices, and/or of contracts between Philips and the distributors or sellers of the Recalled Devices.

640. The Recalled Devices are products such as medical devices that affect human health and life; and therefore, they implicate the broad public policy of protecting human health and life.

641. Enforcement of a privity requirement would unfairly prejudice Plaintiffs and the members of the Class, who relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

642. In addition, any purported durational limit to the implied warranty of usability would be procedurally and substantively unconscionable and otherwise unenforceable.

643. An attempted durational limit would be procedurally unconscionable because Philips unilaterally imposed the time limitation on the implied warranty of usability, without affording Plaintiffs and the Class any bargaining authority. Indeed, the limitation was drafted by Philips, without any input or consent from Plaintiffs and the Class, and it was presented to Plaintiffs and the Class as a settled term in the User Manual issued for each Recalled Device. As such, Plaintiffs and the Class had no meaningful choice in setting any temporal limitation on the warranty.

644. Such a limitation would be substantively unconscionable because there was a substantial disparity in the parties' relative bargaining power. As Plaintiffs allege, prior to and at the time it sold the Recalled Devices to Plaintiffs and the Class, Philips was aware of the latent defect regarding PE-PUR foam degradation in the Recalled Devices. Yet, Philips suppressed information concerning the latent defect from Plaintiffs and the Class. If a durational limit existed, it would mean Philips had abused its superior knowledge of the Defect to manipulate the temporal limits of the implied warranty of usability in such a manner so that it could avoid coverage relating to the latent defect while it continued manufacturing and selling the Recalled Devices containing PE-PUR foam, including to Plaintiff and the Class. Plaintiffs and the Class had no notice or ability to detect the latent defect.

645. Relatedly, due to Philips' knowing concealment of facts and information concerning the latent defect in the Recalled Devices, any purported durational limitation on the implied warranty of usability would be tolled or waived. Defendants' affirmative acts of concealment were designed to prevent any inquiry concerning the Recalled Devices and to induce Plaintiffs and the Class, who did not have notice of or the ability to detect the latent defect, to purchase and/or use the Recalled Devices that purportedly had the temporal limitation on the implied warranty of usability in place.

646. In addition, any attempt by Philips to limit the term of the implied warranty of usability should not be enforced given that the language purporting to set forth the limitation was not presented to Plaintiffs and the Class in a clear and conspicuous manner.

647. Plaintiffs are not required to give notice to Philips, a remote manufacturer and Philips has had notice of the type and source of claims in this matter for over a year. Further, at a minimum on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements.

648. As a direct and proximate result of Philips' misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

649. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation

of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

650. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

651. Plaintiffs also seek such further relief as the Court deems equitable and just.

TWELFTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

652. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as though fully set forth herein.

653. This claim is brought against the Philips Defendants.

654. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. When they sold the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would be exposed to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam.

655. At the time of sale, Philips provided a User Manual with its CPAP, BiPAP, and ventilator devices. Royal Philips owns the copyright to all, or most, of those User Manuals.

656. Philips' User Manuals for the Recalled Devices contained an express warranty providing that the Recalled Devices "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."[415]

[415] *See, e.g.*, Warranty Exemplars: DreamStation (Exhibit "47" hereto), at 29; REMstar SE (Exhibit "48" hereto), at 21; Trilogy 100 (Exhibit "49" hereto), at 163.

657. Philips breached this express warranty in connection with the sale and distribution of Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth in more detail above, rendering them unsuitable and unsafe for personal use.

658. Plaintiffs and the Class reasonably expected that the Recalled Devices were safe for their ordinary and intended use. Had Plaintiffs and the Class known the Recalled Devices were defective, unsafe for use, and exposed them to the Foam Toxins, they would not have used them.

659. Philips has breached its warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices.

660. To the extent privity may be required, Plaintiffs and the Class can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement.

661. Plaintiffs and the members of the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

662. Plaintiffs and the members of the Class were foreseeable and intended third-party beneficiaries of Philips' sale of the Recalled Devices, and/or of contracts between Philips and the distributors or sellers of the Recalled Devices.

663. The Recalled Devices are medical devices that affect human health and life; and therefore, they implicate the broad public policy of protecting human health and life.

664. Enforcement of a privity requirement would unfairly prejudice Plaintiffs and the members of the Class, who relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

665. In addition, any purported durational limit to the warranties would be procedurally and substantively unconscionable and otherwise unenforceable.

666. An attempted durational limit would be procedurally unconscionable because Philips unilaterally imposed the time limitation on the warranties, without affording Plaintiffs and the Class any bargaining authority. Indeed, the limitation was drafted by Philips unilaterally, and it was presented to Plaintiffs and the Class as a settled term in the User Manual issued for each Recalled Device on a "take it or leave it" basis. As such, Plaintiffs and the Class had no meaningful choice in setting any temporal limitation on the warranty.

667. Such a limitation would be substantively unconscionable because there was a substantial disparity in the parties' relative bargaining power, which Philips used to craft a warranty that unreasonably favors it over the Class. As Plaintiffs allege, prior to and at the time it sold the Recalled Devices to Plaintiffs and the Class, Philips was aware of the latent defect regarding PE-PUR foam degradation in the Recalled Devices. Yet, Philips suppressed information concerning the latent defect from Plaintiffs and the Class. If a durational limit were enforceable, it would mean Philips had abused its superior knowledge of the Defect to manipulate the temporal limits of the warranties in such a manner so that it could avoid coverage relating to the latent defect while it continued manufacturing and selling the Recalled Devices containing PE-PUR foam, including to Plaintiff and the Class. Plaintiffs and the Class had no notice or ability to detect the latent defect.

668. Relatedly, due to Philips' knowing concealment of facts and information concerning the latent defect in the Recalled Devices, any purported durational limitation on the warranties would be tolled or waived. Philips' affirmative acts of concealment were designed to prevent any inquiry concerning the Recalled Devices and to induce Plaintiffs and the Class, who

did not have notice of or the ability to detect the latent defect, to purchase and/or use the Recalled Devices that purportedly had the temporal limitation on the warranties.

669. In addition, any attempt by Philips to limit the term of the warranties should not be enforced given that the language purporting to set forth the limitation was not presented to Plaintiffs and the Class in a clear and conspicuous manner.

670. Plaintiffs are not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for over a year. Further, at a minimum on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements.

671. As a direct and proximate result of Philips' breach of its express warranty, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

672. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiffs and the Class reasonably expected that the Recalled Devices were safe for their ordinary and intended use.

673. As a direct and proximate result of Philips' misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

674. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation

of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

675. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

676. Plaintiffs also seek such further relief as the Court deems equitable and just.

THIRTEENTH CLAIM FOR RELIEF

COMMON LAW FRAUD
(Individually, on Behalf of the Class, and on Behalf of the Subclasses)

677. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as if fully set forth herein and further allege as follows:

678. This claim is brought against the Philips Defendants.

679. At all relevant times, Philips knew that the Recalled Devices posed serious health risks to users.

680. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers, including Plaintiffs, Class members, and their physicians, because to do otherwise would have resulted in users seeking safer alternatives to treat their breathing issues.

681. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-

PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

682. Philips concealed from Plaintiffs and Class members and failed to disclose to them material information regarding the serious health risks posed to users of the Recalled Devices by, among other things, failing to include material information in its packaging, labels, advertisements, promotional materials, websites, and other communications and disclosures.

683. Philips was under a duty to disclose to, among others, Plaintiffs, Class members, and their physicians, the serious health risks posed to users of the Recalled Devices because: (a) Philips was in a superior position to know the risks associated with the use of the Recalled Devices; (b) Philips was in a superior position to determine whether or not to disclose or conceal information regarding the Recalled Devices in its packaging, labels, advertising, websites, and other communications and disclosures; (c) Philips had a duty to fully disclose all facts related to the serious health risks to users posed by the Recalled Devices; (d) Philips knew that Plaintiffs, Class members and their physicians could not reasonably have been expected to learn or discover the serious health risks posed by use of the Recalled Devices prior to purchasing, leasing, recommending, and/or using the Recalled Devices in general, and particularly given the representations, concealed material information, and omissions by Philips in its packaging, labels, advertising, websites, and other communications and disclosures; and (e) Philips has a duty to disclose information related to the health and safety of its products, including the Recalled Devices.

684. By concealing and failing to disclose the Defect, Philips intentionally, knowingly, and recklessly allowed its packaging, labels, advertisements, promotional materials, websites, and

other communications and disclosures to mislead Plaintiffs, Class members, and their physicians, into believing that the Recalled Devices were safe for use.

685. Philips knew that its concealment and omissions regarding the Defect in its packaging, labels, advertisements, promotional materials, websites, and other communications and disclosures were false, deceptive, inadequate, and misleading.

686. The information undisclosed and concealed by Philips was material. A reasonable person, including Plaintiffs and Class members, would find information that impacted on users' health and well-being, such as the serious adverse health risks associated with the use of the Recalled Devices, to be important when deciding whether to use the Recalled Devices.

687. As a result of such deceptive packaging, labels, advertisements, promotional materials, websites, and other communications and disclosures, Plaintiffs and the Class members justifiably and reasonably believed the Recalled Devices were safe for use.

688. Philips intentionally, knowingly, and recklessly concealed and omitted information about the Defect and its related serious health effects in its packaging, labels, advertisements, promotional materials, websites, and other communications and disclosures regarding the Recalled Devices to induce Plaintiffs and Class members to purchase, lease, and/or use the Recalled Devices.

689. Plaintiffs and Class members justifiably and reasonably relied on the omissions by Philips and used the Recalled Devices. Reasonable consumers would have been expected to rely on these omissions, in part, because they are omissions that seriously impact users' health and well-being.

690. Philips' fraudulent conduct actually and proximately caused harm to Plaintiffs and Class members because absent Philips' concealment and omissions, Plaintiffs and Class members

would have behaved differently and would not have used the Recalled Devices

691. As a direct and proximate result of Philips' misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

692. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

693. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

694. Plaintiffs also seek such further relief as the Court deems equitable and just.

FOURTEENTH CLAIM FOR RELIEF

STATE-LAW PRODUCT LIABILITY ACT CLAIMS
(Individually, and on Behalf of Certain State-Specific Subclasses)

695. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as is fully set forth herein and further allege as follows:

696. The Recalled Devices were defectively designed and manufactured, as the Recalled Devices used PE-PUR foam that exposed users to the Foam Toxins.

697. Breathing devices that cause users to inhale and ingest carcinogens, VOCs, and other hazardous materials are, by definition and as detailed above, defectively manufactured. As a direct and proximate cause of Philips' and PolyTech's material omissions, misrepresentations, and

concealment of material information regarding the health effects to users of the Recalled Devices, Plaintiffs have suffered exposure that creates and/or increases the risk that Plaintiffs will develop cancer and other diseases, necessitating notice to all Class members, sufficient funding for the tests and evaluations of each Class member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

698. Philips' and PolyTech's conduct in defectively manufacturing the Recalled Devices was reckless and taken with wanton and willful disregard for the health of Plaintiffs and Class members.

699. Defendants are strictly liable for the harm caused by or contributed to by the defectively manufactured Recalled Devices.

700. Plaintiffs note that to the extent any claims are deemed not to be subsumed, whether in prior or future orders by the Court, stipulations, or other court filings, Plaintiffs assert all available common law and statutory causes of action available to them under the laws of the states and territories upon which their claims rest.

701. **Connecticut Product Liability Act, Conn Gen. Stat. §§ 52-572m**. Connecticut Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows.

702. Connecticut Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Connecticut Product Liability Act, Conn Gen. Stat. §§ 52-572m under the theories of strict liability – manufacturing defect, strict liability – failure to warn, strict liability – design defect, negligence, negligence per se, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, punitive damages, and consumer protection claims.

703. The claims above are brought against the Philips Defendants and the PolyTech Defendants.

704. Plaintiffs bring this claim on behalf of themselves and the Connecticut Subclass.

705. **Indiana Product Liability Act, Ind. Code §§ 34-20-1-1**. Indiana Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows.

706. Indiana Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Indiana Product Liability Act, Ind. Code §§ 34-20-1-1 under the theories of strict liability – manufacturing defect, strict liability – failure to warn, strict liability – design defect, negligence, negligence per se, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages.

707. The Indiana PLA does not subsume express or implied warranty claims asserted in this Complaint, and therefore Plaintiffs assert those claims under the common law and/or other applicable law causes of action enumerated herein.

708. The claims above are brought against the Philips Defendants and the PolyTech Defendants.

709. Plaintiffs bring this claim on behalf of themselves and the Indiana Subclass.

710. **Kansas Product Liability Act, Kansas Stat. Ann. 60:3301, *et seq***. Kansas Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as thought fully set forth herein and further allege as follows.

711. Kansas Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Kansas Product Liability Act, Kansas Stat. Ann. 60-3301 et seq. under the theories of strict liability – manufacturing defect, strict liability – failure to warn, strict liability – design

defect, negligence, negligence per se, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages.

712. The claims above are brought against the Philips Defendants and the PolyTech Defendants.

713. Plaintiffs bring this claim on behalf of themselves and the Kansas Subclass.

714. **New Jersey Product Liability Act, N.J.S.A. 2A:59C-2**. New Jersey Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows:

715. New Jersey Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the New Jersey Product Liability Act, N.J.S.A. 2A:59C-2 under the theories of strict liability – manufacturing defect, strict liability – failure to warn, strict liability – design defect, negligence, negligence per se, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, punitive damages, and consumer protection claims.

716. The New Jersey PLA does not subsume express warranty claims asserted in this Complaint, and therefore Plaintiffs assert that claim under the common law and/or other applicable law causes of action enumerated herein.

717. The claims above are brought against the Philips Defendants and the PolyTech Defendants.

718. Plaintiffs bring this claim on behalf of themselves and the New Jersey Subclass.

719. **Ohio Product Liability Act, Ohio Rev. Code § 2307.72(A) & (B)**. Ohio Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully

set forth herein and further allege as follows.

720. Ohio Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Ohio Product Liability Act, Ohio Rev. Code § 2307.72(A) & (B) under the theories of strict liability – manufacturing defect, strict liability – failure to warn, strict liability – design defect, negligence, negligence per se, breach of express warranty, breach of implied warranty, negligent misrepresentation, wrongful death, survival, loss of consortium, punitive damages, and consumer protection claims.

721. The Ohio PLA does not subsume claims alleging or sounding in fraud asserted in this Complaint, and therefore Plaintiffs assert those claims under the common law and/or other applicable law causes of action enumerated herein.

722. The claims above are brought against the Philips Defendants and the PolyTech Defendants.

723. Plaintiffs bring this claim on behalf of themselves and the Ohio Subclass.

724. **Tennessee Product Liability Act, Tenn. Code Ann. § 29-28-101 *et seq***. Tennessee Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows.

725. Tennessee Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Tennessee Product Liability Act, Tenn. Code Ann. § 29-28-101 et seq. under the theories of strict liability – manufacturing defect, strict liability – failure to warn, strict liability – design defect, negligence, negligence per se, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages.

726. The claims above are brought against the Philips Defendants and the PolyTech

Defendants.

727. Plaintiffs bring this claim on behalf of themselves and the Tennessee Subclass.

728. **Washington Product Liability Act, Wash. Rev. Code Ann. § 7.72.010 *et seq***. Washington Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as though fully set forth herein and further allege as follows.

729. Washington Plaintiffs, based upon the facts previously alleged herein, allege causes of action under the Washington Product Liability Act, Wash. Rev. Code Ann. § 7.72.010 et seq. under the theories of strict liability – manufacturing defect, strict liability – failure to warn, strict liability – design defect, negligence, negligence per se, breach of express warranty, breach of implied warranty, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages.

730. The Washington PLA does not subsume claims alleging or sounding in fraud asserted in this Complaint, and therefore Plaintiffs assert those claims under the common law and/or other applicable law causes of action enumerated herein.

731. The claims above are brought against the Philips Defendants and the PolyTech Defendants.

732. Plaintiffs bring this claim on behalf of themselves and the Washington Subclass.

733. As a direct and proximate result of Philips' misconduct, Plaintiffs and Class members have been presently injured and suffered damages, in that their use of the Recalled Devices resulted in past and present exposure, increasing their risk of developing cancer, respiratory disease, cardiovascular disease, and other illnesses, causing them the present and ongoing need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease and disease process.

734. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

735. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

736. Plaintiffs also seek such further relief as the Court deems equitable and just.

FIFTEENTH CLAIM FOR RELIEF
(Declaratory Judgment under the Declaratory Judgment Act)

737. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as is fully set forth herein.

738. An actual, substantial, and justiciable controversy has arisen and exists between Plaintiffs and Class members and Philips herein and their respective rights, obligations, and duties with respect to the presence, accumulation, toxic invasion, and/or persistence of the Foam Toxins in the bodies of Plaintiffs and Class members, as a result of Philips' acts and/or omissions.

739. By reason of the foregoing, Plaintiffs and Class members seek a declaratory judgment against Philips that Philips is liable and responsible for the introduction of the Foam Toxins into Plaintiffs' and Class members' bodies and all equitable and/or injunctive relief, and such other relief as the Court may Order, that the Court deems reasonable and appropriate in relation thereto.

VIII. RELIEF SOUGHT BY THE CLASS

740. Plaintiffs reallege and incorporate by reference the allegations set forth throughout the Complaint as is fully set forth herein and further allege as follows:

741. Plaintiffs and the proposed Class have sustained exposure to Philips' Foam Toxins

resulting in the presence, accumulation, toxic invasion, and/or persistence of the Foam Toxins in their bodies, as a result of Defendants' acts and/or omissions.

742. As a result, Plaintiffs and the Class seek equitable and/or injunctive relief for each of the causes of action alleged herein; neither Plaintiffs nor the Class are seeking any compensatory damages for personal injuries through any class-wide claims asserted herein.

743. Plaintiffs seek, on behalf of themselves and Class members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of, a fund to adequately finance the costs of necessary testing, evaluations and screening, and other necessary medical consultations for the early detection of illness, disease and disease process.

744. In addition, Plaintiffs seek, as damages and/or equitable relief, establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins.

745. Plaintiffs also seek such further relief as the Court deems equitable and just.

IX. RELIEF NOT REQUESTED AND RESERVATION OF RIGHTS

746. None of the causes of action asserted herein seeks damages or other relief for economic losses for the cost of, or cost to, repair a Recalled Device, or personal injuries allegedly attributable to Plaintiffs' and Class members' use of a Recalled Device. Such claims will be governed by the Consolidated Third Amended Class Action Complaint for Economic Losses, filed October 10, 2022 (ECF 785), and/or the Amended Master Personal Injury Complaint, to be filed by October 24, 2022, and any additional Short Form Complaints that may be filed (or as otherwise agreed by the parties). The named Plaintiffs in this Complaint expressly reserve their right to seek damages or other relief for other economic losses and/or personal injuries they may have suffered, regardless of whether those damages are sought through causes of action alleged herein or otherwise.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following judgment:

a. Certifying this Action as a class action;

b. Appointing Plaintiff(s) as Class Representative(s), and appointing undersigned counsel as Class Counsel to represent the Class and each Subclass;

c. A finding that Philips and PolyTech are liable pursuant to the above-enumerated causes of action;

d. Awarding appropriate preliminary and/or final injunctive relief;

e. An award of the costs of clinical evaluations, diagnostic testing, and consultations for the early detection of illness, disease, and disease processes; or in the alternative, equitable relief in the form of a court-supervised fund for the costs of medical monitoring;

f. The establishment of a panel of scientists to study the effects on the human body of exposure to the Foam Toxins;

g. An award of attorneys' fees and costs;

h. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest; and

i. Such other and further relief as this Court may deem equitable and just.

XI. JURY DEMAND

Plaintiff and the Class and Subclasses demand a trial by jury on all issues so triable.

Dated: October 17, 2022

Respectfully submitted,

/s/ Sandra L. Duggan
Sandra L. Duggan, Esquire
LEVIN SEDRAN & BERMAN LLP
510 Walnut Street, Suite 500
Philadelphia, PA 19106
(215)592-1500 (phone)
sduggan@lfsblaw.com

/s/ Kelly K. Iverson
Kelly K. Iverson, Esquire
LYNCH CARPENTER, LLP
1133 Penn Avenue, 5th Floor
Pittsburgh, PA 15222
(412) 322-9243 (phone)
kelly@lcllp.com

/s/ Christopher A. Seeger
Christopher A. Seeger, Esquire
SEEGER WEISS LLP
55 Challenger Road, 6th Floor
Ridgefield Park, NJ 07660
(973) 639-9100 (phone)
cseeger@seegerweiss.com

/s/ Steven A. Schwartz
Steven A. Schwartz, Esquire
CHIMICLES SCHWARTZ KRINER & DONALDSON-SMITH LLP
361 West Lancaster Avenue
One Haverford Centre
Haverford, PA 19041
(610) 642-8500 (phone)
steveschwartz@chimicles.com

Plaintiffs' Co-Lead Counsel

William Audet, Esquire
AUDET & PARTNERS, LLP
711 Van Ness, Suite 500
San Francisco, CA 94102
(415) 568-2555 (phone)
waudet@audetlaw.com

Michael J. Blakely, Jr., Esquire
POPE MCGLAMRY, P.C.
3391 Peachtree Road, NE, Suite 300
Atlanta, GA 30326
(404) 523-7706 (phone)
mjblakely@pmkm.com

Ron Anthony Austin, Esquire
RON AUSTIN LAW, LLC
400 Manhattan Blvd.
Harvey, LA 70058
(504) 227-8100 (phone)
raustin@ronaustinlaw.com

Virginia Marie Buchanan, Esquire
LEVIN, PAPANTONIO, RAFFERTY, PROCTOR, BUCHANAN, O'BRIEN, BARR & MOUGEY, P.A.
316 S Baylen Street, Suite 600
Pensacola, FL 32502
(850) 435-7023 (phone)
vbuchanan@levinlaw.com

Shanon J. Carson, Esquire
BERGER MONTAGUE PC
1818 Market Street, Suite 3600
Philadelphia, PA 19103
(215) 875-4656 (phone)
scarson@bm.net

Lauren Sanderson Miller, Esquire
HAGENS BERMAN SOBOL SHAPIRO LLP
1301 2nd Ave, Suite 2000
Seattle, WA 98101
(206) 623-7292 (phone)
laurenm@hbsslaw.com

Michael F. Ram, Esquire
MORGAN & MORGAN
Complex Litigation Group
711 Van Ness Avenue, Suite 500
San Francisco, CA 94102
(415) 358-6913 (phone)
MRam@forthepeople.com

Dena C. Sharp, Esquire
GIRARD SHARP LLP
601 California Street, Suite 1400
San Francisco, CA 94108
(415) 981-4800 (phone)
dsharp@girardsharp.com

Jason Rathod, Esquire
MIGLIACCIO & RATHOD LLP
412 H St NE, Suite 302
Washington, DC 20002
(202) 509-5951 (phone)
jrathod@classlawdc.com

Joyce Chambers Reichard, Esquire
KELLEY & FERRARO, LLP
Ernst & Young Tower
950 Main Avenue, Suite 1300
Cleveland, OH 44113
(216) 575-0777 (phone)
jreichard@kelley-ferraro.com

David S. Stellings, Esquire
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 Hudson St., 8th Floor
New York, NY 10013
(212) 355-9500 (phone)
dstellings@lchb.com

Plaintiffs' Steering Committee

/s/ D. Aaron Rihn
D. Aaron Rihn, Esquire
ROBERT PIERCE & ASSOCIATES, P.C.
707 Grant Street, Suite 125
Pittsburgh, PA 15219
(412) 281-7229 (phone)
arihn@peircelaw.com

Peter St. Tienne Wolff, Esquire
PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP
One Oxford Centre - 38th Floor
Pittsburgh, PA 15219
(412) 263-2000 (phone)
psw@pietragallo.com

Co-Liaison Counsel

Miriam Fresco Agait, Esquire
RUBENSTEIN LAW, P.A.
9130 S. Dadeland Blvd, Suite PH
Miami, FL 33156
(305) 661-6000 (phone)
mfagrait@rubensteinlaw.com

Ava Cavaco, Esquire
MESHBESHER & SPENCE
1616 Park Avenue
Minneapolis, MN 55404
(612) 339-9121 (phone)
acavaco@meshbesher.com

Kristina Anderson, Esquire
HENSLEY LEGAL GROUP, PC
117 E. Washington Street, Ste 200
Indianapolis, IN 46204
(317) 472-3333 (phone)
kanderson@hensleylegal.com

Claire E. Kreider, Esquire
GAINSBURGH, BENJAMIN, DAVID, MEUNIER & WARSHAUER, LLC
2800 Energy Centre, 1100 Poydras Street
New Orleans, LA 70163
(504) 522-2304 (phone)
cberg@gainsben.com

Kathryn L. Harrison, Esquire
CAMPBELL & LEVINE, LLC
1700 Grant Building, Ste. 1700
Pittsburgh, PA 15219
(412) 261-0310 (phone)
kharrison@camlev.com

Inez Johnson Ross, Esquire
ONDER LAW, LLC
110 East Lockwood, 2nd Floor
St. Louis, MO 63119
(314) 227-7674 (phone)
iross@onderlaw.com

Syreeta Defrance-Poindexter, Esquire
BABIN LAW, LLC
22 E. Gay Street, Suite 200
Columbus OH 43215
(614) 761-8800 (phone)
syreeta.poindexter@babinlaws.com

Ashley B. DiLiberto, Esquire
MESSA & ASSOCIATES, P.C.
123 S. 22nd Street
Philadelphia, PA 19103
(215) 568-3500 (phone)
adiliberto@messalaw.com

Ian W. Sloss, Esquire
SILVER GOLUB & TEITELL LLP
One Landmark Square, 15th Floor
Stamford, CT 06901
(203) 325-4491 (phone)
isloss@sgtlaw.com

Kevin W. Tucker, Esquire
EAST END TRIAL GROUP LLC
6901 Lynn Way, Suite 215
Pittsburgh, PA 15208
(412) 877-5220 (phone)
ktucker@eastendtrialgroup.com

Leadership Development Committee

Roberta D Liebenberg, Esquire (Chair)
FINE, KAPLAN AND BLACK, R.P.C.
One South Broad Street, 23rd Floor
Philadelphia, PA 19107
(215) 567-6565 (phone)
rliebenberg@finekaplan.com

Arthur H. Stroyd, Jr., Esquire (Vice Chair)
DEL SOLE CAVANAUGH STROYD LLC
3 PPG Place, Suite 600
Pittsburgh, PA 15222
(412) 261-2172 (phone)
astroyd@dscslaw.com

Lisa Ann Gorshe, Esquire (Vice Chair)
JOHNSON BECKER PLLC
444 Cedar Street, Ste 1800
Saint Paul, MN 55101
(612) 436-1852 (phone)
lgorshe@johnsonbecker.com

Settlement Committee

Alyson L. Oliver, Esquire
OLIVER LAW GROUP PC
1647 W. Big Beaver Road
Troy, MI 48084-5380
(248) 327-6556 (phone)
(248) 436-3385 (fax)
aoliver@oliverlawgroup.com

Time & Expenses Subcommittee

Kyle G.A. Wallace, Esquire
SHIVER HAMILTON CAMPBELL LLC
3490 Piedmont Road, Suite 640
Atlanta, Georgia 30305
(404) 593-0020 (phone)
kwallace@shiverhamilton.com

John Albanese, Esquire
BERGER MONTAGUE PC
1229 Tyler Street, Suite 205
Minneapolis, MN 55413
(612) 594-5997 (phone)
jalbanese@bm.net

John G. Emerson, Esquire
EMERSON FIRM PLLC
2500 Wilcrest, Suite 300
Houston, TX 77042
(800) 55-8449 (phone)
jemerson@emersonfirm.com

Robert H. Klonoff, Esquire
ROBERT H. KLONOFF, LLC
2425 SW 76th Ave
Portland, OR 97219
(503) 291-1570 (phone)
klonoff@usa.net

Kenneth J. Grunfeld, Esquire
GOLOMB SPIRIT GRUNFELD, P.C.
1835 Market Street, Suite 2900
Philadelphia, PA 19103
(215) 985-4169 (phone)
kgrunfeld@GolombLegal.com

Jonathan M. Jagher
FREED KANNER LONDON & MILLEN LLC
923 Fayette Street
Conshohocken, PA 19428
(610) 234-6486 (phone)
jjagher@fklmlaw.com

R. Scott Long, Esquire
HENDRICKSON & LONG, PLLC
214 Capital Street
Charleston, WV 25301
(304) 346-5500 (phone)
scott@handl.com

Kelly Hyman, Esquire
THE HYMAN LAW FIRM, P.A.
515 North Flagler Drive, Suite P-300
West Palm Beach, FL 33401
(561) 538-7198 (phone)
kellyhyman@thehymanlawfirm.com

Stephen R. Basser, Esquire
BARRACK, RODOS & BACINE
One America Plaza
600 West Broadway, Suite 900
San Diego, CA 92101
(619) 230-0800 (phone)
sbasser@barrack.com

Tiffany Marko Yiatras, Esquire
CONSUMER PROTECTION LEGAL, LLC
398 Hutchinson Road
Ellisville, MO 63011
(314) 541-0317 (phone)
tiffany@consumerprotectionlegal.com

Francis J. “Casey” Flynn, Jr., Esquire
LAW OFFICE OF FRANCIS J. FLYNN, JR
422 South Curson Avenue
Los Angeles, California 90036
(314)-662-2836 (phone)
casey@lawofficeflynn.com

Randi Kassan, Esquire
MILBERG COLEMAN BRYSON PHILLIPS GROSSMAN PLLC
100 Garden City Plaza, Suite 500
Garden City, NY 11530
(516) 741-5600 (phone)
rkassan@milberg.com

James J. Rosemergy, Esquire
CAREY DANIS & LOWE
8235 Forsyth Boulevard, Suite 1100
Saint Louis, MO 63105
(314) 725-7700 (phone)
jrosemergy@careydanis.com

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was filed via the Court's CM/ECF system on this 17th day of October 2022 and is available for download by all counsel of record.

/s/ D. Aaron Rihn
D. Aaron Rihn, Esquire
PA I.D. No.: 85752
ROBERT PEIRCE & ASSOCIATES, P.C.
707 Grant Street
Suite 125
Pittsburgh, PA 15219
Tel: 412-281-7229
Fax: 412-281-4229
arihn@peircelaw.com